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# How "Low" Can You Go? New Plaintiff Theories of Low Dose Exposure

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Proving that a plaintiff was in fact exposed to your client's product in any meaningful amount, if at all, has become a bothersome and expensive endeavor for plaintiff's attorneys. That pesky "dose-response" thing keeps interfering with their windfall recoveries. Furthermore, certain segments of society believe that the use of manufactured or refined chemicals, in any amount, is *per se* harmful to animals and the environment. They take their arguments to the government, directly to the people, and, as counsel knows, to the courts.

This article was prompted by a series of stories in a prominent newspaper about new theories of how exposure to small amounts of chemicals may in fact be causing all sorts of chronic ills. We will first review some of the publicity surrounding these new theories, and then analyze recent court cases where plaintiffs claimed that low, or in some instances, unquantifiable, exposures to chemicals caused harm. In order to avoid the costly prospect of expert testimony on dose, or the bothersome fact that a plaintiff may not have been exposed to your client's chemical at all, plaintiffs have created several theories to avoid the "dose" question altogether. So, how low can they go?

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### A Big Dose of Propaganda...

Low-level chemical exposure "injuries," or even just the potential for injuries, have gained quite a bit of media coverage these days. Plaintiffs' attorneys, environmental activists and the news media have played on the fears of the American public to perpetuate class action law suits against chemical manufacturing companies. However, the dangers facing the public are not from the low-level exposure to chemicals, but from the high-levels of incomplete or misinterpreted information to which they are exposed.

In 2005, the Wall Street Journal published a series of articles by Peter Waldman chronicling various lowlevel "hazards" threatening our health. In his first installment, Waldman reports on the everyday items that activists alleged pose a "threat" to our health and well-being. Peter Waldman, Toxic Traces: Common Industrial Chemicals in Tiny Doses Raise Health Issue, Wall St. J. 1 (July 25, 2005). Plastic baby bottles contain low levels of bisphenol A, allegedly causing altered brain behavior. Cosmetics, shampoo, drug capsules, and plastic toys contain low levels of phthalates that supposedly cause genital abnormalities. Lastly, drinking water's low levels of perchlorate purportedly cause brain and behavior changes. Id.

His next installment tells the tale of Matthew Davis, a child whose life was halted by his overindulgence in tuna. Peter Waldman, Fish Line: Mercury and Tuna: U.S. Advice Leaves Lots of Questions, Wall St. J. A1(Aug. 1, 2005). The third installment reports

about how activists try to grow our fears through scientific interpretations pointing to pregnant women and their children as most at risk for genital and reproductive birth defects due to phthalates. Peter Waldman, Under the Microscope From an Ingredient in Cosmetics, Toys a Safety Concern, Wall St. J. A1 (Oct. 4, 2005). And yes, those are the same phthalates that exist in our babies' bottles and toys, as well as nail polish, shampoo and cosmetics. Id. What better way to create or maintain hysteria than to point to everyday essentials and toiletries and blame them for illnesses in our country's adults, children and unborn babies?

Waldman's final installment goes beyond our own country's alleged industrial hazards and reports on a Chinese doctor's report, resulting in multiple lawsuits in California, that turned out to be bogus. Peter Waldman, Clarification of Chinese Study Absolved Chromium-6; Did Author Really Write It? Echo of Erin Brockovich, Wall St. J. A1 (Dec. 23, 2005). Dr. Zhang published a study in 1987, indicating that people were dying of cancer from exposure to trace amounts of chromium-6 in rural China. Then ten years later, when Dr. Zhang was unable to provide substantiation for his conclusions after defense attorneys in several large lawsuits tracked him down, he retracted his own study. Unfortunately, the original study continues to have an impact on regulatory bodies.

In a similar vein, Ben & Jerry's Ice Cream has been known for its environmental activism over the years. In 2001, they issued a brochure about the dangers of dioxin and how no level of dioxin was safe. Steven Milloy, Fox News, A Scoop of Debunkey Monkey, Please, <a href="http://www.foxnews.com/">http://www.foxnews.com/</a> story/0,2933,831,00.html> (Feb. 2, 2001). They even lobbied the EPA to reduce the maximum safe level of dioxin. Id. As it turns out, while Ben & Jerry's was promoting the hysteria of low-level exposure, they should have been looking for change closer to home. Ben & Jerry's ice cream was tested and found to contain 200 times the EPA's acceptable level of dioxin and 2000 times the acceptable level to which they were lobbying the EPA to change the maximum.

Plaintiffs' attorneys have tried and failed to further these hyped-up cases against chemical companies for damages allegedly caused by low-level chemical exposure. In July 2005, Florida plaintiffs' attorneys filed a \$5 billion suit against DuPont for unsubstantiated claims that Teflon produced toxic PFOA fumes when heated. Elizabeth M. Whelan, Sc.D., M.P.H., American Council on Science and Health, The New Litigation Against Teflon Won't Stick, <a href="http://">http:// www.acsh.org/factsfears/newsID.592/ news\_detail.asp>(July 19, 2005). The irony of this argument is that Teflon does not even contain PFOAs. Id. While the Florida case has yet to be resolved, another low-level exposure case was thrown out by the Michigan Supreme Court. In July 2005, Michigan plaintiff attorneys attempted to sue Dow Chemical Co. for alleged exposure to dioxin. David Eggert, Detroit News, Court Rules for Dow in Dioxin Case, <a href="http://">http://</a> www.detnews.com/2005/metro/

0507/21/B07-254188.htm> (July 21, 2005). None of the plaintiffs had any physical injuries, but the attorneys still sued the company for the possibility of future injuries. *Id.* Clearly, the plaintiffs' attorneys are promulgating this low-level hysteria by filing suit for people who are not, and may never be, injured. Luckily, the Michigan Supreme Court ruled that the residents could not sue Dow Chemical because they had no injuries and the threat of future injury was not enough to force Dow to screen them. *Id.* 

Interestingly, the Center for Disease Control (CDC) has taken the opposite tack - that there is no proven link between low-level exposure to these chemicals and injuries to humans. Several days before the Wall Street Journal published the first installment of the Waldman "Toxic Traces" chronicles and Florida attorneys filed the Teflon suit, the CDC issued a press release that low levels of chemicals present in the human body are not a "health risk." Center for Disease Control, Third National Report on Human Exposure to Environmental Chemicals, < http:// www.cdc.gov/exposurereport/> (July 21, 2005). The CDC concluded that the levels of chemicals in the human body have actually decreased over the years due to a reduction in pollution. According to the Competitive Enterprise Institute's review of the report, "humans are living longer, healthier lives than ever before, in large part because we have chemicals to clean our water, disinfect our hospitals, and grow our food." Press Release, CDC Report: Chemicals in Human Body Not a Problem, < <a href="http://www.cei.org/">http://www.cei.org/</a>

gencon/003,04701.cfm> (July 22, 2005).

Journalists, activists and plaintiffs' attorneys have preyed on our fears to further their own agendas. In the end, the science will prevail and the public will be able to live their longer lives contemplating how they got sucked into the media frenzy of low-level chemical exposure mania.

### ... But a Little Dose of Exposure

Fortunately, the courts have been less willing than the press to give in to the hysteria. Arguing that exposures small enough to cause cancerous mutation in a "single abnormally transformed cell," a plaintiff claiming that exposure to benzene from working on a barge caused his squamous cell cancer created the "oncogene" theory of causation. Willis v. Amerada Hess Corp., 2002 WL 140542 (S.D.N.Y.), aff'd, 379 F.3d 32 (2d Cir. 2004). Plaintiff had worked on a barge as a seaman from 1986 to 1995. In late 1995, after complaining of pain in his jaw, nose and throat, he was diagnosed with cancer. The cancer quickly spread, and he died in 1996. Id at

The plaintiff's wife sued his employer under the Jones Act individually and as a class representative. In support of the case, the plaintiff provided two reports from the same expert, Dr. Bidanset. In the first report, Dr. Bidanset stated that "presently evidence suggests that cancers arise from a single abnormally transformed cell," and that "the concept of a threshold or no effect level of exposure to carcinogens is controversial. Since a carcinogen can initiate a change in the [single] subject cell, there really is

no safe exposure." The doctor conceded, though, that "there is however strong evidence that a dose-response relationship exists for carcinogens." Id at \*4. After reviewing several cancer studies, the court found, "he doesn't specify what the method of exposure [in the studies] was" or how the studies drew the correlation between exposure and cancer. Dr. Bidanset concluded that plaintiff's exposure "to these carcinogenic hydrocarbons must have been significant . . . the aggressiveness of Mr. Willis' cancer would lead one to conclude that he was intensely exposed" to the benzene. Id at \*4. The court noted that Dr. Bidanset admitted that this last statement "is based on speculation." Id at

Dr. Bidanset gave a second written report, where he reviewed Coast Guard regulations on monitoring exposure to benzene, OSHA standards for benzene exposure, material safety data sheets, and an article from Environmental Health Perspectives. Id at \*5 - 6. Still, no dose was established. At his deposition, Dr. Bidanset set forth his "oncogene" theory: "There are certain toxic events that do not demonstrate a dose-response relationship. There is no threshold value for carcinogenic activity and you do not need to have a dose-response relationship associated with a low level exposure." Id at \*8. Dr. Bidanset based his oncogene theory that exposure to benzene caused plaintiff's cancer on "just basically, my background experience and reading. I couldn't point you to a specific reference." Id at \*8. The old *ipse dixit*.

The court rejected Dr. Bidanset's opinion, excluded his testimony, and granted summary judgment to the de-

fendants. The court walked through the factors set out in the Federal Reference Manual on Scientific Evidence, "Reference Guide to Toxicology." Relying on the third factor, "evidence of exposure," the court found that Dr. Bidanset provided no evidence that the plaintiff was even exposed to benzene — he was on the ship when benzene may have been present, but there was no evidence that he was near to or exposed to the benzene. *Id* at \*10 - 11.

The court ultimately rejected the oncogene theory. Dr. Bidanset had admitted it was controversial. Also called the "linear non-threshold model," that one unquantified exposure can cause a certain disease, the court rejected the testimony under Daubert. The theory "cannot be falsified, nor can it be validated. To the extent that it has been subject to peer review and publication, it has been rejected by the overwhelming majority of the scientific community . . . It is merely a hypothesis." Id at \*14 (citation omitted). The court concluded that, under Dr. Bidanset's theory, specific causation as a result of exposure to a defendant's product would be unprovable. That is, it would be impossible to determine which exposure to a chemical caused the cancer, because people are exposed to carcinogens "in the ambient environment on a daily basis." *Id* at \*15.

# Can Too *Little* of a Bad Thing Hurt You?

Dr. Bidanset's failure (beyond the *ipse dixit* problem) ultimately may have been his inability to state directly that the plaintiff even had been exposed to diesel exhaust. This is apparently a

common problem. In Parker v. Mobil Oil Corp., 793 N.Y.S.2d 434, 438 (2005), the state court also rejected the "linear non-threshold model," finding that it has been "flatly rejected as merely a hypothesis." In that case, the plaintiff again alleged that exposure to benzene from his work as a gas station attendant for 17 years caused his AML. Plaintiff's experts were unable to establish a dose of exposure, instead, they described plaintiff's usual daily activities and then concluded that his exposure was "extensive" and that he had "abundant" and "ample" opportunity for exposure. Id at 437 (internal quotations omitted).

The court rejected the non-threshold theory. Although the parties conceded that exposure to benzene may cause leukemia (general causation), the plaintiff's experts were unable to make a scientific connection between plaintiff's specific level of exposure, and the AML. *Id* at 438-39. The court described the non-threshold theory as "if a lot of something is bad for you, a little of the same thing . . . must be so in some degree." *Id* at 438 (citations omitted). The Court noted that this theory has been resoundingly rejected by other courts.

The court, using a three-step analysis recommended by the World Health Organization, found that the plaintiff was unable to show that an exposure occurred, let alone that it caused the AML. Plaintiff did not establish his exposure level to the benzene (step 1). His experts were similarly unable to show evidence of step 2, that the scientific literature shows that exposure to the toxin can cause the illness claimed *and* the level of exposure that will cause that illness. *Id* at 437. Simply put, "the plaintiff

presented no evidence of the concentration of benzene in gasoline to which he was exposed." *Id* at 438. Absent evidence in support of step 1 of the WHO test, step 2 is meaningless. Thus the non-threshold model by its nature cannot meet two out of three steps of the WHO test, and was properly rejected by the court.

#### **Plutonium Is Still Not Safe**

Meeting with a little more success on a chronic, low dose exposure to radiation claim, a plaintiff was able to persuade a district court that his expert's methodology of arriving at her conclusion was sound, despite the absence of specific studies linking low dose exposure to plaintiff's chronic myelogenous leukemia. Smith v. General Electric Co., 2004 WL 870832 (D. Mass). The plaintiff was employed at defendant's nuclear power station between 1972 and 1988. During that time he was exposed both internally and externally to low levels of ionizing radiation. Defendants did not contest (for purposes of the motion to exclude plaintiff's expert witness) plaintiff's calculation of the dose of plutonium and americium he received. Id at \*1 and n.2.

Rather, defendants attacked plaintiff's expert's scientific basis for her opinion. Plaintiff's expert proposed to testify that even small, inhaled doses of this radiation can penetrate the exterior of the bone (through emitting radiation) in order to cause mutations in genetic material in the blood marrow, causing CML. Defendants argued that studies fail to show an elevated risk of CML from inhalation of radiation emitters, and that the likelihood of emissions pen-

etrating the bone to strike a pluripotent cell were "infinitesimally small" and "a very, very rare event." *Id* at \*2. Defendants tried, it seems, to characterize plaintiff's theory under the linear non-threshold model.

Focusing on the scientific reliability standards for admissibility of expert testimony under F.R.E. 702 and *Daubert*, the court reasoned that its role was not to "conclude a case simply because I am convinced that one side's science is superior to the other's." *Id* at \*4.

Instead, the court found that competing views of general causation should be determined by the jury's traditional role of weighing "cross examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Id* at \*5. The court found that plaintiff's experts were not mere "poseurs or witnesses for hire. They are serious scientists with controversial views . . . but views that are no so divorced from a scientific method of investigation that they can be dismissed as quackery or armchair conjecture." Id at \*4. Thus, the plaintiffs would be allowed to present their theory to the jury.

Finally, in contrast to *Willis*, an Ohio court opened the door to allowing expert testimony as to both general and specific causation despite the lack of scientific evidence that expo-

sure to a substance in any dose can even induce the plaintiffs' symptoms. In a recent Ohio sick building case, the court reversed the exclusion of expert testimony as to general causation only, despite the expert's failure to establish a no observable effects level, or dose-threshold, for mold. Terry v. Ottawa County Board, 2006 WL 45769 (Ohio App.). In that case, the plaintiffs' expert testified that for certain substances a NOEL cannot be established because it is impossible to do human testing. Molds, according to the expert, are "potentially toxic, they're potentially pathogenic, they're infectious." Id at \*10.

The court stated that, despite the lack of a quantifiable dose-response relationship between mold exposure and plaintiffs' symptoms, an expert can still give an opinion as to both general and specific causation if there is a proper scientific method to arriving at these conclusions. *Id* at \*10. In this case, however, the expert did not link the exposure to the symptoms through any scientifically reliable method such as differential diagnosis. Rather, the court found, he relied solely on the temporal relationship between exposure and symptoms. Thus, the trial court had properly barred the expert's testimony as to specific causation (but not as to general causation). Id at \*13.

The Ohio Ccourt left open the obvious question raised by the expert's testimony about human testing, that is, if there are no studies establishing a dose-response level of mold exposure to a set of symptoms (according to the expert), how does the expert know that exposure to mold caused those symptoms in the plaintiffs? Apparently, when an expert performs a sound differential diagnosis as to specific causation, "the need for evidence of threshold levels is obviated." *Id* at \*9

#### **Conclusion**

Studies into whether lower doses or even a single exposure to a chemical will cause disease in humans are certainly a worthwhile pursuit. However, publicity before the proof can only result in mis-information. It can also result in lawsuits. We've shown that plaintiffs are starting to challenge established dose-response methodology, with both success and failure. How low can they go? Only time will tell.