Legal Backgrounder

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Roundup Cases May Be a New Example of an Old Problem: The *Post Hoc* Fallacy

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Recent verdicts by several California juries in lawsuits by plaintiffs alleging they developed cancer from exposure to glyphosate, the active ingredient in the widely used herbicide Roundup®, highlight a recurring problem in the civil justice system with respect to the use of "expert" scientific evidence: the *post hoc ergo propter hoc* fallacy.

This fallacy, which is observable in many aspects of daily life, presumes that if one thing follows something else, that first thing must have caused the second thing. For example, a person who develops a fever after eating leftovers the night before might erroneously assume the two are related. A person who lets a friend use her cell phone to make a call and notices the returned phone is not working properly might erroneously assume the friend is to blame. Many superstitions, for instance a black cat crossing a person's path providing a warning of a subsequently occurring accident or mishap, provide further examples of the *post hoc* fallacy.

In the area of product liability, the *post hoc* fallacy refers to a false assumption that if an adverse medical condition follows a person's use of, or exposure to, a product, the person's condition must have been caused by that product. Courts generally require expert evidence to establish causation based on sound science, but the courtroom testimony of experts can sometimes cloud unscientific conclusions in the minds of jurors. The Mississippi Supreme Court recognized this potential eighty years ago, stating that although the *post hoc* fallacy has been repeatedly dispelled by courts, it "has the characteristic of an endless renewal."[1]

When juries buy into the *post hoc* fallacy, it can result in serious adverse consequences for society. Product liability law is replete with unfortunate examples of courts failing to adequately screen expert testimony presented to layperson jurors, allowing the *post hoc* fallacy to lead jurors down an improper path that jeopardizes the health and welfare of others. This Legal Backgrounder discusses a few of these examples, each of which bear similarities to the current Roundup litigation.

The Morning Sickness Drug Bendectin®

The Food and Drug Administration (FDA) approved the use of Bendectin in 1956 to treat nausea

[1] *Kramer Serv., Inc. v. Wilkins*, 186 So. 625, 627 (Miss. 1939) (recognizing *post hoc* fallacy and dismissing action where plaintiff who was diagnosed with cancer after a piece of glass from a hotel ceiling fell on him alleged the fallen glass caused his cancer).

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and vomiting during pregnancy.[2] By the 1980s, the product had become the leading treatment for these ailments in the United States and in many other parts of the world.[3] Around this time, plaintiffs' lawyers began bringing lawsuits against Bendectin's manufacturer, alleging the drug caused birth defects. These lawsuits were predicated on a few studies in the late 1970s and early 1980s associating Bendectin use with specific birth defects.

Hundreds of lawsuits were eventually filed. Faced with enormous potential liability exposure, the manufacturer stopped selling Bendectin worldwide in 1983. Meanwhile, the FDA engaged in continuous study of the drug during the 1980s, concluding at every turn the data failed to show an association between Bendectin use and injury. Some trial court judges, however, allowed juries to hear expert testimony based more on speculation about Bendectin than sound science. Plaintiffs' lawyers obtained multiple verdicts against the manufacturer, enabling the *post hoc* fallacy to win the day and keep a safe and effective drug off the market.

Relief in the Bendectin litigation would later come in the way of a landmark U.S. Supreme Court decision, but it came too late as a practical matter. In 1993, the U.S. Supreme Court decided *Daubert v. Merrill Dow Pharmaceuticals, Inc.*,[4] instructing federal judges to act as "gatekeepers" to exclude unreliable expert testimony in a case involving Bendectin. "Expert evidence," the Court appreciated, "can be both powerful and quite misleading because of the difficulty in evaluating it," which requires judges to make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."[5]

In the case of Bendectin, though, the damage was done. The myriad lawsuits combined with adverse publicity kept this FDA-approved drug off the market. Pregnant women who suffered severe morning sickness were deprived for decades of the leading medicine that could help them.

The Vaccine Preservative Thimerosal

Thimerosal is a compound used in medicines and vaccines, as well as various other products, to prevent spoilage and the growth of bacteria. It was developed in the 1920s and became a widely used preservative in vaccines for children. The Centers for Disease Control and Prevention (CDC) states that "Thimerosal use in medical products has a record of being very safe" and that "Data from many studies show no evidence of harm caused by the low doses of thimerosal in vaccines."[6]

Nevertheless, in the 1990s, a rise in the number of diagnoses of autism, which coincided with an expanded vaccine schedule for infants, resulted in parents and plaintiffs' lawyers asserting thimerosal caused autism in children. In the courts, plaintiffs' lawyers supported these allegations through experts' pseudoscience that perpetuated this *post hoc* fallacy. The claims attracted significant media attention, which prompted many parents to reject vaccinating their children. In 1999, the U.S. Public Health Service responded to the public's concern and confusion by recommending thimerosal be removed as a preservative from most vaccines "as a precautionary measure" in spite of "no evidence that thimerosal in vaccines was dangerous."[7]

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[2] *See* Bendectin History, at https://www.bendectin.com/en/.

[3] *See id.* (stating that Bendectin accounted for 82% of all U.S. prescriptions to treat nausea and vomiting during pregnancy in 1980).

[4] 509 U.S. 579 (1993).

[5] *Id.* at 593-94, 595 (quotation omitted).

6 Thimerosal in Vaccines, Centers for Disease Control and Prevention, at https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html.

[7] Understanding Thimerosal, Mercury, and Vaccine Safety, Centers for Disease Control and Prevention (2013), at https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/ downloads/vacsafe-thimerosal-color-office.pdf.

This public health scare rooted in the *post hoc* fallacy has had lasting impacts in society. It gave rise to an anti-vaccination campaign in which many parents—to this day—refuse to vaccinate their children based on the unsupported belief that vaccines cause autism. The result is that unvaccinated children needlessly suffer from disease.

The Anti-Depressant Zoloft®

Litigation involving the drug Zoloft provides a helpful contrast to courts' failure to recognize the *post hoc* fallacy in the Bendectin and thimerosal examples. Zoloft is approved by the FDA to treat depression and other mental health disorders, and can provide critical benefits to a vulnerable population. During the past decade, plaintiffs' lawyers filed hundreds of lawsuits against Zoloft's manufacturer, alleging the medication caused birth defects.

In 2016, Washington Legal Foundation highlighted a decision by Judge Cynthia M. Rufe in *In re Zoloft Products Liability Litigation*,[8] the multi-district litigation (MDL) in the U.S. District Court for the Eastern District of Pennsylvania that consolidated birth defect claims against the manufacturer.[9] "Judge Rufe painstakingly reviewed the plaintiffs' counsel's proposed expert testimony, each time recognizing that the evidence could not overcome the hurdle of showing that ingesting Zoloft® caused birth defects, and was therefore inadmissible."[10] She dismissed *all* of the MDL claims alleging the medication caused birth defects.

As a result, patients suffering from depression and other mental health disorders could continue taking Zoloft without the threat of unwarranted litigation leading to the drug's withdrawal from the market. Judge Rufe's ruling underscores the importance of judges faithfully exercising their "gatekeeping" rule to exclude unreliable expert evidence that perpetuates the *post hoc* fallacy.

The Herbicide Roundup®

The current litigation alleging glyphosate in Roundup causes Non-Hodgkin's Lymphoma (NHL) contains several earmarks of the examples discussed involving the *post hoc* fallacy. Like these other products, glyphosate provides important societal benefits—namely, protection against devastating crop losses—and has been studied extensively for decades. In fact, more than 800 studies have been submitted to the Environmental Protection Agency (EPA) and European and other regulators that support the safety of using glyphosate-based herbicides.[11]

In particular, the EPA, National Cancer Institute, Institute of Environmental Health Sciences, and National Institute for Occupational Safety and Health have found no association between glyphosate-based herbicides such as Roundup and cancer.[12] An outlier, which plaintiffs' lawyers have seized upon to support the more than 18,000 cases filed involving Roundup, is a 2015 listing by the International Agency for Research on Cancer (IARC) of glyphosate as "probably carcinogenic."

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[8] 176 F. Supp. 3d 483 (E.D. Pa. 2016).

[9] *See* Victor E. Schwartz, In re Zoloft *MDL Judge's Rejection of Causation Testimony Provides Helpful Lesson for Bench and Bar*, 34:13 Legal Backgrounder (Wash. Legal Found. May 13, 2006), available at https://s3.us-east-2.amazonaws.com/washlegal-uploads/upload/legalstudies/legalbackgrounder/051316LB_Schwartz.pdf.

[10] *Id.* at 2.

[11] *See* Glyphosate's Impact on Human Health and Safety, Bayer, at https://www.bayer.com/en/glyphosate-impact-on-human-health-and-safety.aspx?gclsrc=aw.ds.

[12] *See id.*

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Importantly, IARC did not conduct an independent study to support its conclusions. The organization's reputation has also come into question in the past based on determinations that red meat, beer, cell phones, and hot beverages such as coffee and tea are probably carcinogenic. It is also telling that after IARC's listing (and after the influx of litigation), the EPA and other regulatory authorities around the world reaffirmed that glyphosate-based herbicides do not pose a cancer risk.

The issue of whether reliable evidence exists that could demonstrate to a jury that glyphosate can cause cancer came before the Roundup MDL Judge Vince Chhabria of the U.S. District Court for the Northern District of California in 2018. He concluded that the "evidence, viewed in its totality, seems too equivocal to support any firm conclusion that glyphosate causes NHL."[13] Nevertheless, he allowed plaintiffs' to present evidence of a cancer risk to a jury, reasoning "a trial judge should not exclude an expert opinion merely because he thinks it's shaky."[14]

Several large verdicts followed, threatening the continued use of glyphosate-based herbicides worldwide. Discontinuing use of these products could have catastrophic impacts on agriculture and food production around the world. Up to 40 percent of the world's potential crop population is lost annually due to weeds, pests, and diseases. Glyphosate-based herbicides are an indispensable tool for farmers to prevent such losses and make the most effective use of farmland.

Juries are still out, so to speak, with respect to how they view scientific evidence involving glyphosate. Lay jurors, however, may not fully appreciate differences in the reliability of expert evidence or the real-life societal consequences of imposing massive liability related to Roundup use. It is up to judges to act as gatekeepers in evaluating the reliability of the available science and not allow this litigation to become the latest example of the "endless renewal" of the *post hoc* fallacy.

[13] *In re Roundup Prods. Liab. Litig.*, MDL No. 2741, 2018 WL 3368534, at *1 (N.D. Cal. July 10, 2018).
[14] *Id.* at *2.

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