For The Defense™

dri
The magazine for defense, insurance and corporate counsel

September 2025

Toxic Torts + Environmental Law, and Medical Liability + Health Care Law

Including . . .

From Transcription to Trap: AI Scribes, Discovery, and Spoliation

Also in This Issue . . .

DRI Election Spotlight

And More!

By Scott Emery
and Ali Spindler

Offense is the Best Defense:
Tackling the Impediments to Obtaining and Using Genetic Testing in Toxic Tort Cases

Genetic evidence can be persuasive and even dispositive.

Defendants are increasingly obtaining and presenting genetic evidence in their attempts to defeat personal injury claims in a variety of tort cases involving cancers, benign tumors, and a wide range of birth defects, including developmental disorders and delays, and concerning a wide range of products, such as over the counter drugs (e.g., acetaminophen), vaccines, fungicides, glyphosate, paraquat, solvents (benzene adducts), and asbestos fibers. Other cases have involved cancer clusters allegedly caused by particular air or water emissions such as ethylene oxide, alleged medical malpractice before or during birth, and workplace exposures. Ongoing and recently-asserted federal MDLs inevitably will involve genetic issues, including hair relaxer litigation and Depo-Provera birth control litigation. Across the board, courts and commentators generally approve of ordering genetic testing of plaintiffs as part of discovery.

Genetics 101

Genetics refers to the study of specific genes, while genomics is the study of the entire human genome. The genome encompasses a person's full set of DNA, or genetic material. It contains information about a person's growth and development, traits such as hair and eye color, and the potential to develop various diseases and medical conditions. The field of genomics has rapidly developed since the Human Genome Project was completed in 2003 and provided a molecular roadmap for the human being. By studying the genome, scientists have identified new methods for diagnosing, treating, and preventing disease.

Obtaining and Using Genetic Evidence in Civil Cases

Genetic evidence can be persuasive and even dispositive. In fact, (i) many courts have relied on genetic causation evidence to preclude plaintiffs' experts from testifying about causation issues when those experts have failed to rule out genetics as the cause of an injury, and (ii) some courts have used such evidence as a basis to grant summary judgment in favor of defendants on causation issues.

Scott Emery of Segal McCambridge Singer & Mahoney is a lawyer because his parents were hellbent on his becoming the first person on either side of his family to go to college and the only career options they proposed to him were doctor, lawyer, and businessman, which, because he was squeamish about blood and had no idea what "business" was, really left him with only one option, which he enthusiastically embraced (if only they had told him about the movie/rock star career options!). Now he represents Fortune 500 companies (so that's what business is!) and regularly requests blood samples from plaintiffs in toxic tort cases (which he does even though blood still makes him squeamish — because he knows that it is the right thing to do), all the while living on Siesta Key (or in NYC) with his wife and their 3.6-pound Maltese, Falcon (get it?), who, along with their 170-pound college senior of a son, who was named after an actor who played a key character in Some Kind of Wonderful (is there a theme here?), root for the Detroit Lions year after year — no matter what. **Ali Spindler** is a partner at Irwin Fritchie Urquhart Moore & Daniels, where her practice focuses on toxic tort and products liability litigation. She is responsible for building and managing teams of expert witnesses from a variety of scientific disciplines, guiding them through all phases of litigation – including expert reports, depositions, and trial testimony – and briefing and arguing motions to exclude experts on both sides. Ali is also dedicated to improving well-being in the legal profession, particularly for working parents and junior attorneys, and is a member of her firm's Attorney Development, Pro Bono, and Diversity, Equity & Inclusion Committees.

Compelling Genetic Testing

Although genetic testing has been less commonly performed in civil litigation than in paternity or criminal cases, that appears to be changing as courts continue to permit the collection of blood samples for genetic analysis in more and more civil cases.

Legal Support

Plaintiffs do sometimes consent to genetic testing, particularly in situations where they already have undergone some sort of genetic testing in connection with their medical treatment. But, more often than not, plaintiffs require defendants seeking DNA samples to move to compel their production. Rule 35 of the Federal Rules of Civil Procedure – and similar rules in state courts – will permit physical examination of a plaintiff whose physical health is in controversy. Such examination may include genetic testing, which courts have been ordering more commonly in various contexts, including in the toxic tort context.

Practical Considerations

With the legal underpinnings of a successful motion to compel genetic testing in mind, there are also a number of practical issues to contend with. The first is how to obtain the evidence necessary to support the legal arguments. This will require a detailed review of the medical records for potentially relevant factors such as prior cancers, familial cancers, prior genetic testing (of any kind), prior blood draws, and the like. (Obtaining complete copies of a plaintiffs' medical records can be very difficult because of certain institutional and legal barriers, so substantial effort may need to be expended on this front.) It will also require deposing the plaintiff on these issues.

The second practical consideration is what type of sample to request (e.g., blood, saliva, or buccal swab). Always request a blood sample (case law and evidence of prior blood draws can be used to demonstrate the non-invasiveness of blood sampling) because it is the best type of sample available in that, for example, it would not contain contaminants that samples extracted from a person's mouth necessarily would.

Third, ask the Court to order whole genome sequencing (WGS), which essentially means that all data contained in the blood sample would be extracted and saved. Reporting could be limited to, say, certain genes, which could be a useful point to raise in situations where privacy issues are significant. Another benefit to WGS is that, should a party wish to pursue information about a gene or genes for which no results were reported, the party would not need to go back to the Court to request yet another blood sample but would simply need to obtain approval from the Court to receive the results of the gene(s) newly at issue.

Fourth, have a sample collection service and a laboratory to extract the data and report results. This is not necessarily as easy, logistically speaking, as it may sound.

Fifth, retain an expert or experts to support a motion to compel. Because of the nature of laboratory reporting of genetic testing results, which is clinical- and diagnostic-based, a geneticist would need to review and interpret the results. It would, therefore, make sense to retain the same geneticist to submit an affidavit in support of any motion to compel.

Using Genetic Evidence

Defendants have used genetic testing successfully in many contexts. These examples could be addressed to the Court in response to a plaintiff's motion to preclude a defense genetic causation expert or, perhaps more appropriately, on a defense motion to preclude a plaintiff's expert from rebutting genetic causation evidence. For example, in Hendrix ex rel. G.P. v. Evenflo Co., plaintiff alleged that an infant car seat failed to protect her child during an accident, and he sustained injuries that caused him to develop Autism Spectrum Disorder ("ASD") and paralysis. Plaintiff's medical expert opined that the accident was the sole cause of the ASD, and he claimed to have eliminated other causes for it. He based that on the fact that the infant had prior genetic testing for Fragile X Syndrome (linked to developmental and cognitive disorders), which was normal. The court found the expert's opinions unreliable, because he failed to consider other potential causes for the child's ASD, including at least 91 other genes linked to autism.

Additionally, in Bowen v. E.I. De Pont De Nemours and Co., plaintiffs claimed that children developed birth defects from their mothers' exposures to agricultural products during pregnancy. The court ordered one child to undergo genetic testing, which revealed that the child had an inherited mutation known to cause CHARGE syndrome, a disorder associated with developmental abnormalities during early childhood. Plaintiff's medical expert opined that the child's genetic variant interacted with defendants' product to cause her injury. After finding that the expert was unqualified to testify about genetics, and his opinions were not based on reliable science, the court found "no evidence of any cause other than [plaintiff's

The past several years have seen an increase in litigation overall and in toxic tort litigation, attributable in part to more attorney advertising and litigation funding.

[1] *In re Acetaminophen — ASD-ADHD Prods. Liab. Litig., 2024 U.S. Dist. LEXIS 121259, 2024 WL 335760.*
[2] *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., 2024 U.S. App. LEXIS 17369, 2024 WL 3423709.*
[3] *Bowen v. E.I. DuPont de Nemours & Co., 906 A.2d 787 (2006).*
[4] *In re Roundup Prods. Liab. Litig., 713 F. Supp. 3d 681, 2024 U.S. Dist. LEXIS 19154, 2024 WL 348811.*
[5] *Richter v. Syngenta AG (In re Paraquat Prods. Liab. Litig.), 730 F. Supp. 3d 793, 2024 U.S. Dist. LEXIS 70452.*

genetic] mutation" and upheld summary judgment in favor of defendants.

Further, for substances with identified molecular biomarkers, or "signatures" of exposure, courts have permitted genetic evidence as probative of specific causation. In Henricksen v. ConocoPhillips Co., plaintiff claimed to have developed Acute Myelogenous Lymphoma ("AML") from exposure to benzene. AML can be classified as primary, meaning that it is "idiopathic" or unrelated to external factors, or secondary, meaning that it is caused by external factors like chemical exposures. Researchers have identified specific chromosomal changes (biomarkers) that indicate whether a person is likely to have primary or secondary AML. In Henricksen, plaintiff showed no signs of any chromosomal abnormality, which strongly suggested that his AML was primary, not caused by benzene exposure. Additionally, the plaintiff's cancer was a genetic subtype not associated with chemical exposures. The court held that plaintiff's medical expert unreasonably failed to consider genetic evidence, as well as other causes of plaintiff's AML, and excluded him as an expert.

The bottom line is that courts across the country have found genetic causation opinions to be both reliable and important to their decision-making processes. As the court noted in Marousek v. Neb. Pediatric Prac., the "majority of jurisdictions that have addressed the issue [have held] that an expert witness called by the defense to testify about causation... may testify about 'possible' causes of the plaintiff's injury." The court continued:

> Defendant need not prove another cause, he only has to convince the trier of fact that the alleged negligence was not the legal cause of the injury. In proving such a case, a defendant may produce other 'possible' causes of the plaintiff's injury. These other possible causes need not be proved with certainty or more probably than not. To fashion such a rule would unduly tie a defendant's hands in rebutting a plaintiff's case, where as here, plaintiffs expert testifies that no other cause could have caused plaintiffs injury. The burden would then shift and defendant would then bear the burden of positively proving that another specific cause, not the negligence established by plaintiff's expert, caused the injury. Certainly, this is much more than what should be required of a defendant in rebutting a plaintiff's evidence.

An even more stark example of the value and, hence, admissibility of genetic testing can be found in In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., a case involving a group of more than 1,700 plaintiffs alleging that they suffered shingles or shingles-related injuries from a vaccine containing varicella-zoster virus ("VZV"). The defendant moved to exclude the plaintiffs' medical expert's opinion on causation because the expert did not rule out a reactivated wildtype VZV from previously contracted chickenpox as a cause of plaintiffs' shingles. Both sides agreed that only a polymerase chain reaction (PCR) test could conclusively establish whether the plaintiffs' injuries were caused by the vaccine or the wildtype virus. After the court ordered plaintiffs to serve laboratory records demonstrating that their injuries resulted from the vaccine-strain VZV – and after no plaintiff provided such records (i.e., the plaintiffs produced no PCR test results) – the court dismissed all 1,700+ cases for failure to prove specific causation.

In other words, not only is genetic testing generally considered relevant and admissible, but the lack of such testing on the part of a plaintiff can prove devasting to a plaintiff's case by rendering that plaintiff unable to meet his or her burden with respect to causation. In fact, courts have dismissed cases where, even in the absence of genetic testing, plaintiffs' experts have failed to fully explore and reliably rule out genetics as a potential cause of a given plaintiff's injury.

In sum, if plaintiffs wish to meet their burdens to prove general and specific causation in this case, it would behoove them to agree to genetic testing, for, without it,

[6] *Milward v. Acuity Specialty Prods. Group, 639 F.3d 11, 2011 U.S. App. LEXIS 5727, 31 I.E.R. Cas. (BNA) 1812, CCH Prod. Liab. Rep. P18,600.*
[7] *Watts v. Pneumo Abex, LLC, 106 Cal. App. 5th 248, 2024 Cal. App. LEXIS 686, 326 Cal. Rptr. 3d 786, 2024 WL 4611827.*
[8] *Foster v. Evonik Corp., 620 F. Supp. 3d 482, 2022 U.S. Dist. LEXIS 141206, 2022 WL 3214406.*
[9] *Ortega v. United States, 2021 U.S. Dist. LEXIS 188969, 2021 WL 4477896.*
[10] *Duffina v. Stolthaven New Orleans, LLC, 2024 U.S. Dist. LEXIS 74230, 2024 WL 1734115.*
[11] *In re: Hair Relaxer Marketing Sales Practices and Products Liability Litigation, Case No. 1:23-cv-00818 (N.D. IL).*
[12] *In re: Depo-Provera (Depot Medroxyprogesterone Acetate) Products Liability Litigation (MDL decision pending).*
[13] *The arduous but increasingly successful scientific journeys to understand DNA, genetics, and hereditary cancers are described in very accessible and readable books such as the recently published A Fatal Inheritance: How a Family Misfortune Revealed a Deadly Medical Mystery by Lawrence Ingrassia and the Pulitzer Prize winning book from 2010, The Emperor of All Maladies: A Biography of Cancer by Siddhartha Mukherjee.*

they will not be able to rule out genetics as a cause of the disease at issue and, therefore, may not be able to meet their burdens of proof against defendants.

Dispelling Plaintiffs' Arguments

Despite the body of cases supporting the use of genetic evidence in civil cases, plaintiffs often attempt to preclude genetic testing by arguing that such evidence would be inadmissible at trial. In toxic tort cases, plaintiffs argue that breaking open a person's genetic makeup is unduly burdensome, disproportionate to the needs of the case, and unduly prejudicial under Rule 403. Plaintiffs also object under Rule 401, arguing that evidence of any genetic mutation is irrelevant because such a mutation would, at best, prove other potential causes of the disease at issue, without ruling out causation from toxic exposure.

The most well-known example of such arguments arises in the context of the BAP1 mutation in mesothelioma cases. Scientists have been divided as to whether inherited BAP1 mutations can cause mesothelioma, independent of asbestos exposure, or whether such a mutation simply increases the likelihood of developing mesothelioma after exposure. Given this uncertainty, plaintiffs will argue that evidence of an inherited BAP1 mutation is irrelevant, because defendants cannot prove that it causes mesothelioma without asbestos exposure.

Defendants have scientific evidence to defeat those arguments, at least for some conditions and some germline (inherited) mutations. This is illustrated by the previously cited Bowen and Ortega summary judgment rulings in favor of defendants, which asserted genetic causation defenses. Moreover, a recent study by Dr. Leonel van Zyl and colleagues provides powerful evidence for genetic causes of some cancers, independent of a toxicant: Nielsen DM, Hsu M, Zapata M 3rd, Ciavarra G, van Zyl L., Bayesian analysis of the rate of spontaneous malignant mesothelioma among BAP1 mutant mice in the absence of asbestos exposure. Sci Rep. 2025;15(1):169. Published 2025 Jan 2. doi:10.1038/s41598-024-84069-w (open access).

The study by Dr. van Zyl and team brings together multiple lines of scientific evidence to support that a notable number of mesotheliomas are caused solely by genetic abnormalities, independent of asbestos fibers or other known causes of mesothelioma. Of greater note, the methods used by Dr. van Zyl and colleagues could be used to investigate genomic causation of diseases and conditions involving other alleged or actual toxicants, particularly rare diseases/conditions.

In the Nielsen study, Dr. van Zyl focused on a rigorous statistical re-analysis of a 2016 mouse study by Drs. Testa, Kadariya and colleagues that resulted in the spontaneous onset of malignant mesotheliomas and other core BAP1 cancers in genetically engineered mice given pathogenic germline mutations identical to those in

Table 1. Spontaneous primary malignant tumor types observed in *Bap1*-mutant mice[a]

Tumor types	*Bap1*$^{+/-}$	*Bap1*$^{+/L}$	*Bap1*$^{+/W}$	Total tumors[b]
Ovarian SCST	8	14	16	38
Lung carcinoma	4	1	2	7
Mammary carcinoma	3	1	2	6
Spindle cell tumor	2	3	1	6
Malignant mesotheliomas	1	0	1	2
Lymphoma	0	2	0	2
Colon carcinoma	1	0	0	1
Harderian gland carcinoma	0	1	0	1
Uterine adenocarcinoma	0	1	0	1
Islet cell tumor	0	0	1	1

[a]Among 43 wild-type (*Bap1*$^{+/+}$) littermates (not summarized here), two had mammary carcinoma and two others had lung carcinoma.
[b]Overall number of tumors (66) is greater than the number of mice with cancer (55), because 11 *Bap1*-mutant mice had two independent primary tumors involving different organs. In addition, 12 ovarian SCSTs were bilateral.

[14] *See, e.g., Sotomayor v. Honeywell Int'l, Inc., No. 23STCV01373 (Cal. Super. Ct. March 19, 2024) (order compelling production of a saliva sample for genetic testing purposes in a mesothelioma case); McCabe v. 3M Co., No. 1CCV-22-0001318 (Haw. Cir. Ct. Aug. 30, 2023) (order compelling production of a blood sample for genetic testing purposes in a mesothelioma case); Cusick v. Cusick, 210 A.3d 1199 (R.I. 2019) (affirming order requiring father to submit to genetic testing to determine whether his children were at risk for a certain hereditary disorder); Burt v. Winona Health, No. 16-1085 (DWF/FLN), 2018 U.S. Dist. LEXIS 128944 (D. Minn. Aug. 1, 2018) (reversing order denying defendants' request that plaintiffs submit blood samples for genetic testing relevant to injury causation issues); Kaous v. Lutheran Med. Ctr., 138 A.D.3d 1065 (N.Y. App. Div. 2016) (affirming order compelling genetic testing via blood sample of an infant medical malpractice plaintiff where defendants contended that plaintiff's injuries were caused by a genetic predisposition rather than by malpractice); Craft vs. Eagle, Inc., Case No. 2023-115586 (La. Civ. Dist. Ct. June 13, 2024) (granting defense request for blood test of plaintiff to conduct genomic sequencing in asbestos lung cancer case); see also James M. Beck, Recent Civil Discovery Decisions Addressing Genetic Testing, 18 Mass Torts Litig. 13 (Summer 2020) ("Over the last several years, most decisions have ordered genetic testing for diagnostic or causation purposes.").*

[15] *255 F.R.D. 568, 574-75 (N.D. Fla. 2009), aff'd by Hendrix ex rel. G.P. v. Evenflo, Co., 609 F.3d 1183 (11th Cir. 2010).*

[16] *No. Civ. A. 97C-06-194 CH, 2005 WL 1952859, at *5 (Del. Super. Ct. June 23, 2005).*

[17] *See also Ortega, 2021 U.S. Dist. LEXIS 188969, 2021 WL 4477896 ("Because all evidence in the record indicates that J.A.O.'s neuromuscular failure was caused by a congenital [genetic] condition rather than by negligence on the part of the healthcare providers, both motions [for summary judgment] are granted.").*
605 F. Supp. 2d 1142 (E.D. Wash. 2009).

humans without asbestos exposure. The Kadariya study evaluated BAP1 mutant and wildtype (i.e., without BAP1 mutations) mice under both asbestos-exposed and unexposed conditions. Their experimental design assessed the rate of MM (malignant mesothelioma) in the absence of asbestos exposure in both BAP1 mutant and wildtype mice. Table 1 from the study shows the data regarding the mesotheliomas and numerous other cancers that spontaneously developed in the mice that were given pathogenic germline mutations but were not exposed to asbestos:

As shown above, the investigators reported that the spontaneous rate of MM among germline BAP1 mutant mice was 2 out of 93. That was numerically higher than the rate of MM in wildtype mice as shown at footnote a (0 out of 43). The spontaneous development of mesothelioma in 2 of the 93 genetically engineered mice provided a notable indication that their pathogenic BAP1 mutations could cause MM without exposure to asbestos. However, due to the small experimental sample size, the rate of MM between these two groups was deemed not statistically significant when using Fisher's Exact Test, a point Dr. Testa often mentioned in his testimony in mesothelioma cases.

To re-investigate the statistical significance of the Kadariya data, Dr. van Zyl and team employed a Bayesian power prior analysis approach consistent with the professional recommendations of the American Statistical Association (ASA) to utilize statistical methods better suited to rare, biological situations. Stated simply, the researchers reanalyzed data from the unexposed arm of the Kadariya study using this Bayesian approach, comparing the rate of spontaneous MM among BAP1 mutant mice to wildtype (non-mutated) mice without asbestos exposure. Significantly, Dr. van Zyl and colleagues assessed the effect of BAP1 mutations in two different sets of control populations: (1) wildtype mice in the control group in the Kadariya study; and (2) a historical control dataset (HCD) from an extensive literature search. The development and use of the HCD dataset and Bayesian analysis exemplify the use of well accepted rigorous statistical methodologies that are too seldom utilized but applicable to various contexts.

Using a Bayesian approach to compare the rate of MM in BAP1 mutant mice with wildtype mice in the Kadariya control group, Dr. van Zyl's team reported a 70% probability that the rates reported between these two groups (0/43 in the wildtype mice vs. 2/93 in the BAP1 mutant mice) differed significantly. Thus, whereas the Kadariya study failed to report a statistically significant difference using Fisher's exact test, the Bayesian approach yielded a highly statistically significant difference.

Overall, the Nielsen study demonstrates – with over 95% certainty – that an inherited pathogenic germline BAP1 null variant (mutation) can and will cause spontaneous malignant transformation (i.e., the onset of malignant mesothelioma), independent of external factors (i.e., asbestos exposure). More specifically, the study showed that there is up to a 97.9% probability that pathogenic BAP1 null germline mutations – by themselves - cause malignant transformation (i.e., spontaneous MMs and other cancers) at a rate that is twice the rate when compared to individuals who did not inherit a BAP1 null variant. They stated:

> "The conclusion from each of these approaches is that the rate of spontaneous MM among BAP1 mutant mice is higher than that among wildtype mice (96.7–99.5% probability that the odds ratio is > 1 and 93.2–97.9% probability that it is > 2)."

The Nielsen study also is important because it states several other genomic causation points that are well accepted in the literature, as shown by its many citations.

Conclusion

Given the state of the medicine and science and the general receptivity of courts around the country to genetics-related evidence, toxic tort attorneys should strive to better familiarize themselves with the basics of genetics, genetic causation, and genetics-related defenses, develop an understanding of how and when to gather genetic evidence in their cases, and strategize carefully about presenting genetics-based causation arguments to courts, not merely to defeat motions to preclude genetics-related evidence, but to flip those motions on their heads by making genetic causation-based preclusion motions of their own.

Discuss these topics and more at next year's Toxic Torts and Environmental Law Seminar. Sign up to be notified when registration opens for great savings.

[19] *Marousek. v. Neb. Pediatric Prac., No. CI-18-7181, 2021 Neb. Trial Order LEXIS 3326 (Dist. Ct. Nov. 4, 2021) (overruling plaintiff's motion to bar any testimony relating to the results of plaintiff's genetic testing after mutation of potentially uncertain significance to the plaintiff's seizure disorder found).*

[20] *Id. at *11-12 (quoting Wilder v. Eberhart, 977 F.2d 673, 676-77 (1st Cir. 1992)).*

[22] *MDL No. 2848, 2022 U.S. Dist. LEXIS 219261 (E.D. Pa. Dec. 6, 2022), aff'd, No. 23-1032 (3d Cir. 2024).*

[23] *See, e.g., N.K. v. Abbott Labs., No. 14-CV-4875 (RER), 2017 U.S. Dist. LEXIS 77461, at *12-19 (E.D.N.Y. May 22, 2017) (in case alleging prenatal exposure to drug caused birth defects, excluding plaintiff's expert's testimony and granting summary judgment in favor of defendants because the expert did not adequately rule out genetics as an alternative cause); In re Acetaminophen – ASD-ADHD Prods. Liab. Litig., Nos. 22MD3043 (DLC), 22MC3043 (DLC), 2023 U.S. Dist. LEXIS 224899, at *93-100 (S.D.N.Y. Dec. 18, 2023) (in products liability case, excluding expert testimony that relied upon studies that did not control for genetic confounding); Palmer v. Asarco Inc., No. 03-CV-0498-CVE-PJC, 2007 U.S. Dist. LEXIS 57291, at *30-32 (N.D. Okla. Aug. 6, 2007) (in lead exposure case, excluding toxicologist's opinion because, inter alia, he did not consider genetics, parental intelligence, and psychosocial settings in his differential diagnosis); Lofgren v. Motorola, Inc., No. CV-93-05521, 1998 Ariz. Super. LEXIS 53, at *82-90 (Super. Ct. June 1, 1998) (in trichloroethylene exposure case, precluding expert testimony because doctor did not address genetics when opining on causation of brain cancer).*