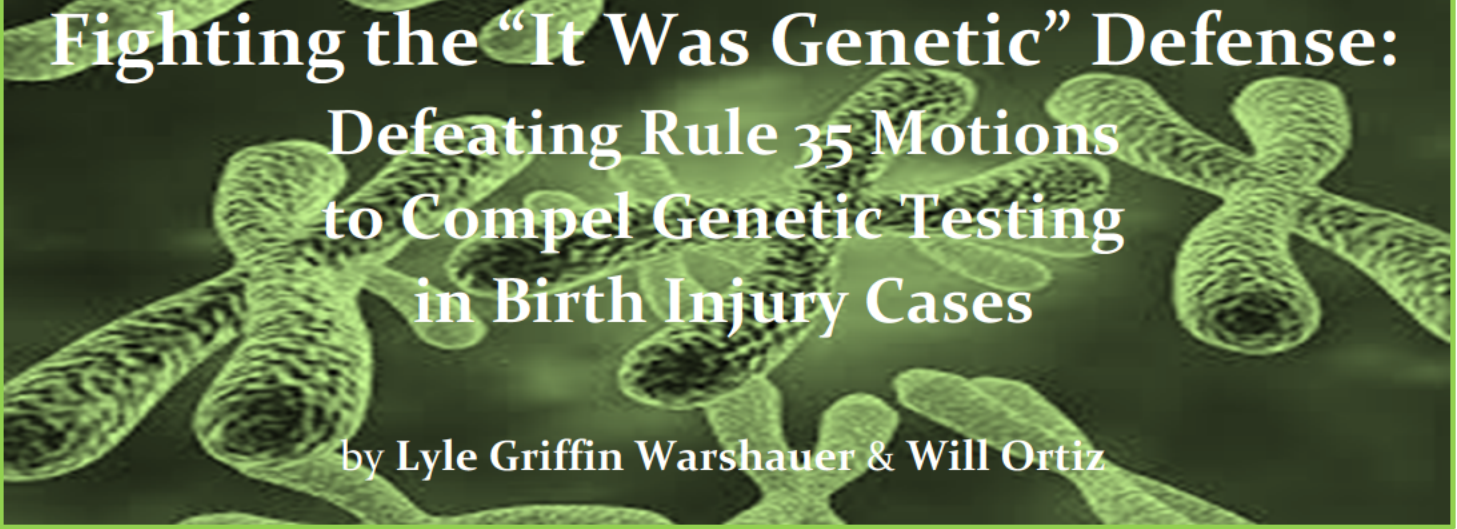


A microscopic image of several chromosomes, showing their characteristic X-shape and internal structure, rendered in a greenish-yellow hue against a dark background.

Fighting the “It Was Genetic” Defense: Defeating Rule 35 Motions to Compel Genetic Testing in Birth Injury Cases

by Lyle Griffin Warshauer & Will Ortiz

If you handle birth injury cases, you have seen this move.

The child suffered a profound hypoxic-ischemic injury during labor and delivery. The records document a clear story: an intrapartum catastrophe. And yet, once litigation begins, the defense offers a different story: maybe this was not caused by what happened in the delivery room at all. Maybe the child had some *undiagnosed, preexisting* genetic, metabolic, or congenital condition that merely looked like hypoxic-ischemic encephalopathy. That is the “genetic mimic” defense.

The theory is simple enough: certain genetic or metabolic conditions can produce findings that overlap with HIE, including neonatal encephalopathy, seizures, abnormal MRI findings, elevated lactate, hypotonia, or developmental delay. From that premise, defendants increasingly move under Discovery Rule 35 pertaining to physical and medical examinations to compel the child to undergo genetic sequencing. They argue that because causation is disputed, the child’s genetic makeup is “in controversy,” and testing should follow.

It should not.

The critical question is not whether genetics can ever be relevant in a birth injury case. Instead, the inquiry is whether the defendant has made a specific, expert-supported showing that this child’s actual clinical presentation creates good cause for the particular genetic test sought. That distinction matters. Rule 35 does not authorize genome mining. It does not permit a defendant to sequence a child’s DNA simply because modern technology makes it possible. And it does not allow a speculative alternative-causation theory to become a compelled medical examination unless the defense can identify a specific suspected condition, tie that condition to the child’s documented findings, and justify the precise scope of testing requested.

This article proceeds in two parts. Part I is the science you need to know: what genetic testing actually does, what the results actually mean, and which genetic or metabolic conditions are commonly invoked as HIE “mimics.” Part II is the practical playbook: how to defeat the motion outright or, if the court is inclined to allow some testing, how to narrow it, protect the child, and keep the defense from turning Rule 35 into a fishing license.

PART I: THE SCIENCE YOU NEED TO KNOW

A. A short primer on DNA

Human DNA is organized into 23 pairs of chromosomes. Our DNA is made up of *exons* and *introns*. The exons are the roughly 20,000 genes — only 1 to 2 percent of the total DNA— that are responsible for making proteins that tell our body how to function. The rest of the DNA (the “introns” or non-coding regions) does not directly make proteins, but it plays a role in how genes work.

A useful analogy: Think of DNA like a book.

- * **Genes (exons)** are the sentences that carry meaning.
- * **Non-coding regions (introns)** are the spaces, punctuation, and margins between sentences.
- * **Chromosomes** are the chapters that organize everything.

That framework lets you understand what each of the genetic tests at issue in these cases actually does — and, just as important, what each one does not do.

B. The Genetic Tests Defendants Typically Ask For

The phrase “genetic testing” sounds singular. Defense motions often use the term as if all genetic tests are basically the same. They are not. The differences matter because each test searches for different things, generates different categories of information, and creates a different level of privacy intrusion. A court cannot meaningfully decide whether testing is justified unless it first understands exactly what kind of testing the defense is asking for.

Defense motions for “genetic testing” tend to lump three very different technologies together. Courts often do not appreciate the differences. Neither do many of the obstetricians and neonatologists the defense designates to opine

that testing should be done. Knowing what is actually on the menu is essential.

Chromosomal Microarray (CMA). CMA looks for missing or extra pieces of DNA across all chromosomes. It does not read the DNA letter by letter; it checks whether any sections are deleted (missing) or duplicated (extra copies). CMA detects copy-number variants, extra or missing whole chromosomes, and certain other chromosome-level problems. It cannot detect small single-letter changes within individual genes, and it cannot detect balanced rearrangements (where pieces of chromosomes have swapped places without any DNA being lost or gained). *Analogy:* imagine checking a book to see if any pages are missing or if extra pages were inserted, without reading the words on each page, that’s CMA.

Whole Exome Sequencing (WES). WES reads the DNA letter by letter, but only in the genes (the exons) —the roughly 1 to 2 percent of the genome that codes for protein. It catches small spelling errors, missing letters, or extra letters within genes that can cause genetic conditions. It does not read the non-coding regions (the other 98 to 99 percent of DNA), and it may miss some larger structural changes. *Analogy:* reading every sentence in the book carefully for typos, but skipping the margins, spaces, and punctuation.

Whole Genome Sequencing (WGS). WGS is the most in-depth and invasive type of testing. It reads nearly all of the DNA, letter by letter — both the genes and the non-coding regions. It finds everything WES finds, plus problems in non-coding regions, structural rearrangements, repeat expansions, and copy-number variants in a single test. Because it produces so much information, some of the non-coding findings are still difficult to interpret. It is also the most expensive. *Analogy:* reading every sentence, every margin note, and

every space in the book looking for any kind of error.

The type of testing at issue matters for Rule 35 practice because the privacy intrusion scales with the test. WGS is the most expansive and the most likely to produce information well beyond anything relevant to the litigation—incidental findings about adult-onset disease risks, carrier status for unrelated conditions, ancestry, paternity, and so on. WGS is, accordingly, the easiest to challenge. WES is the more common defense request and is what most reported decisions involve. CMA is the narrowest of the three and the hardest to oppose categorically, because targeted CMA in a child with specific dysmorphic findings is sometimes clinically appropriate.

C. Reading Genetic Test Results

A single whole-genome sequence can yield millions of genetic variants compared to the standard human reference genome. Almost all are harmless changes or minor deletions that occur frequently in the general population. But the results of a genetic test done on a child with a known neurological disorder can look quite ominous when, in fact, they are not. When a genetic test is run, the lab reports its findings against the clinical indication for the testing, such as HIE, seizures, and encephalopathy. What gets flagged as positive *appears* related to the indication, but the result may have no causal significance whatsoever.

The American College of Medical Genetics and Genomics (ACMG), together with the Association for Molecular Pathology, has established the five-tier framework that labs use to classify variants. Each variant is placed into one of these categories:

- * **Pathogenic** — proven to cause disease
- * **Likely pathogenic** — sufficient evidence to act on clinically, but not definitive
- * **Variant of Uncertain Significance (VUS)** — insufficient or conflicting evidence
- * **Likely benign**
- * **Benign** — proven harmless natural variation

Only pathogenic and likely pathogenic findings are scientifically relevant to the causation question. And pathogenic variants are the least common, with most reported variants being VUS or benign.

A VUS is not a diagnosis. It is not proof of a genetic disease. It is not even proof that the variant matters. It is a laboratory classification saying, in substance, “we do not know.” That uncertainty is precisely why VUS findings are so dangerous in litigation. A defense expert can point to the report, say “there was a genetic finding,” and imply causation without ever proving that the variant caused anything at all.

That move should be cut off early. In briefing and cross-examination, force the distinction between a genetic variant and a genetic diagnosis. The existence of a variant is not the same thing as proof of disease. And proof of disease is not the same thing as proof that the disease caused the child’s injury.

Some facts worth knowing for cross-examination:

- * VUS reports are common, and most VUS findings are eventually reclassified as benign when more data accumulates.¹
- * Pediatric providers who do not specialize in genetics—including the obstetricians and neonatologists the defense often designates— frequently misinterpret VUS reports. In one survey, only about a third of

¹ See Bennett JS et al., *Reclassification of Variants of Uncertain Significance in Children with Inherited Arrhythmia*

Syndromes is Predicted by Clinical Factors, *Pediatr Cardiol* 2019;40:1679, <https://pubmed.ncbi.nlm.nih.gov/31535183/>.

such providers correctly interpreted a mock VUS result.²

- * Many VUS findings are present at population frequencies of 1 to 5 percent — meaning they are also found in plenty of people without any neurological disease.

The bottom line for our cases: only pathogenic findings move the needle on causation. A VUS, no matter how it is dressed up, does not.

D. Known Genetic Mimics of HIE (& How to Tell Them Apart)

The defense will float a list of genetic and metabolic conditions that can “look like” HIE. The good news is that most of them can be ruled out without any genetic testing at all. The clinical history, the newborn screen, the MRI pattern, and basic metabolic labs do most of the work. Here is in a very general sense what you need to know about each category.

Metabolic disorders. Inborn Errors of Metabolism (IEMs) are the broadest category and include genetic conditions where the body cannot properly break down certain proteins, fats, or sugars.³ These conditions are usually easy to distinguish from HIE for three reasons:

- * *Newborn screening catches most of them.* Every state screens for the major genetic metabolic disorders at birth. A normal newborn screening substantially undermines the metabolic mimic claim.
- * *There is no sentinel event.* Babies with metabolic disorders typically appear fine at birth and gradually deteriorate over hours or days, or after an illness, not a sudden

intrapartum collapse. And they often will prove fatal if not recognized and treated early on. A practical example: MCAD deficiency means the child cannot break down certain fats for energy. Without frequent high-carb feedings and short fasting intervals, the child will suffer a life-threatening metabolic crisis. A child with undiagnosed MCAD is not likely to survive infancy — let alone show up years later as the defense theory in your case. Conditions like that can be ruled out without any genetic testing at all.

- * *The MRI looks different.* Some metabolic disorders leave visible footprints on imaging. Maple syrup urine deficiency, for instance, lights up certain myelinating tracts. Non-ketotic hyperglycinemia hits the posterior limb of the internal capsule and globus pallidus on an MRI. Neither matches the basal ganglia and thalamic pattern of profound HIE.

Mitochondrial disorders. These genetic conditions affect how cells produce energy.⁴ These are also easy to distinguish from HIE.

- * *Timing is wrong.* Classic Leigh syndrome, for instance, rarely presents at birth. It usually appears between 3 to 12 months, with developmental regression. True neonatal-onset mitochondrial disease is exceedingly rare and almost always involves multi-system failure (cardiac, hepatic, renal).
- * *Elevated lactate is not enough.* While lactic acidosis is a biomechanical marker of mitochondrial disorders, elevated lactate is also common in perinatal asphyxia. Standing alone, it does not establish a mitochondrial

² See Menke LA et al., *Understanding and interpretation of a variant of uncertain significance (VUS) genetic test result by pediatric providers who do not specialize in genetics*, J Genet Couns 2021, <https://onlinelibrary.wiley.com/doi/abs/10.1002/jgc4.1422>.

³ Most commonly, inborn errors of metabolism include organic acidemias (methylmalonic, propionic), urea cycle disorders, fatty acid oxidation disorders, maple syrup urine disease, and non-ketotic hyperglycinemia.

⁴ These include, for instance, Leigh syndrome, mitochondrial encephalopathy with lactic acidosis, Complex I/III/IV deficiencies, POLG mutations, SURF1 mutations.

QUICK REFERENCE SUMMARY		
HIE vs. Genetic Mimics: At-a-Glance Comparison		
Clinical Feature	Classic HIE	Genetic Mimic (typical)
Sentinel perinatal event	Present (cord prolapse, abruption, etc.)	Absent; gradual onset or inter-current trigger
Newborn screening	Normal (does not exclude HIE)	Often abnormal if metabolic etiology
Apgar scores	Low at 1 & 5 min; resuscitation required	May be normal; neurologic symptoms emerge later
Cord gas / pH	Acidosis (pH < 7.0, base deficit ≥ 12)	Often normal cord gas
MRI timing & pattern	Evolves days 1–7; thalamic/watershed pattern	Fixed pattern; may differ significantly from HIE
Multi-organ involvement	Common (cardiac, renal, hepatic)	Variable; depends on condition
Therapeutic cooling	Initiated; indicates HIE diagnosis confirmed	Would typically be withheld if alternative clear
Family history	Non-contributory	May have relevant history (consanguinity, sibling deaths)

etiology — even though defense experts will sometimes treat it that way.

* *The MRI looks different.* Like certain metabolic conditions, some mitochondrial disorders, like Leigh syndrome, can have visible indicators on an MRI that differ from those performed on a child with HIE. For example, the finds are usually bilateral and symmetric, and distinguishable from watershed/thalamic patterns.

Genetic seizure disorders. A handful of genes (KCNQ2, SCN2A, STXBP1, and others) cause babies to have seizures starting within hours of birth, called **epileptic encephalopathies**. The key point: the seizures in these conditions come from a baby who was delivered normally. The seizures are what *trigger* the workup; they are not the result of anything that happened during labor. A positive gene panel tells you what is causing the seizures, but it tells you nothing about whether labor was managed properly. And if the baby has any structural problem in the brain, the radiologist would have seen it on the first MRI.

Structural brain malformations. Conditions like lissencephaly and polymicrogyria occur where the brain did not form correctly during pregnancy. These form during the second trimester and are visible on the initial MRI — they are not surprise findings on genetic testing. More importantly,

their presence does not preclude a superimposed intrapartum injury. A baby with lissencephaly who suffers birth asphyxia has both conditions. The malformation does not negate the hypoxic injury, and the defense does not get to substitute one for the other.

Chromosomal abnormalities. Down syndrome (trisomy 21), trisomy 13, trisomy 18, and similar conditions are almost always picked up during pregnancy or are obvious at birth from the baby's physical features. They are not the kind of thing that gets discovered years later in litigation.

Coagulation disorders. Factor V Leiden, prothrombin mutations. These come up mostly in neonatal stroke cases, which can occasionally overlap with the HIE presentation.

The practical point is this: most alleged HIE mimics do not require whole-exome or whole-genome sequencing to evaluate. They can usually be assessed through the same clinical evidence already in the record — prenatal history, newborn screening, delivery course, cord gases, neonatal exam, metabolic labs, EEG, MRI pattern, dysmorphology, and family history. If those data point to acute intrapartum HIE, the defense should not be allowed to bypass the existing clinical record and demand open-ended genetic sequencing based on speculation.

RULE 35: THE GATEKEEPING FRAMEWORK

How courts should analyze motions to compel genetic testing in birth injury cases.



Rule 35 is **not** a genome search warrant.

PART II: DEFEATING THE RULE 35 MOTION

Tip 1: Hold the Defense to The Heavy Burden of Rule 35 Exams

Make the court aware that Rule 35⁵ is not garden-variety discovery. The movant bears the burden of establishing good cause, and the showing required under Rule 35 is *greater* than under other discovery rules. *Schlagenhauf v. Holder*, 379 U.S. 104, 118 (1964); *Montana v. Cty of Cape May*, 2013 U.S. Dist. LEXIS 151660 (D.N.J. Oct. 18, 2013) (noting that the good cause standard "must be higher than the general relevancy standard.") This matters because the defense will try to borrow the permissive, "reasonably calculated" relevance standard that governs

interrogatories and document requests. It does not apply. Further, even if good cause is shown, the court must consider whether the examination or testing is appropriate under the specific circumstances of the case, and may require a full hearing on the motion. And it is still within the court's sound discretion to deny the motion. *E.g. Stinchcomb v. U.S.*, 132 F.R.D. 29, 30 (E.D. Pa. Aug. 22, 1990).

A compelled physical examination — and especially compelled genome sequencing of a child — is an intrusion that the rule treats as exceptional. Frame it that way from your opening sentence.

⁵ At least in Georgia, Fed. R. Civ. P. 35 and O.C.G.A. § 9-11-35 are essentially identical for all purposes relevant to this kind of motion. Where state statutes are modeled on the Federal Rules, federal decisions interpreting the federal rule are persuasive authority. *See, e.g. Wellstar Health Systems v.*

Kemp, 324 Ga. App. 629, 638 n.19 (2013). That cuts in a plaintiff's favor: the substantial body of federal Rule 35 case law is available to you in state court, and the federal genetic-testing decisions apply with equal force.

Tip 2: Force the “In Controversy” / “Good Cause” Distinction

The single most important move is to refuse to let the defense collapse two separate requirements into one. Rule 35 permits an examination only when a party's condition “is in controversy,” and only “on motion for good cause shown.” Fed. R. Civ. P. 35(a); O.C.G.A. § 9-11-35(a). These are separate requirements.

Defendants love to argue that because your client filed a lawsuit alleging neurological injury, the condition is “in controversy” — therefore, good cause exists. That conflation does not hold. Filing suit may place the condition in controversy, but that fact alone does not automatically establish good cause. The movant must independently demonstrate a specific, supported, and compelling need for the requested examination. As the United States Supreme Court explained in *Schlagenhauf v. Holder*, Rule 35 requires an affirmative showing that good cause exists for *each particular examination* sought. Conclusory assertions or mere reference to the pleadings is not enough.⁶

In your response brief, separate the two prongs explicitly. Concede “in controversy” if you must — it is usually not worth fighting — and then train all of your fire on good cause, where the defense will almost always be exposed.

Tip 3: Identify the Scope of Testing Requested (Avoid the “Fishing Expedition”)

There are several types of genetic testing that can be requested, some of which are much broader and are more likely to invade the privacy of the patient and the entire family. Testing for a particular gene or disorder is harder to object to,

because presumably there is something in the child's phenotype or history that points to a specific potential abnormality. However, most requests for genetic testing in birth injury litigation are non-specific; rather, the request is for testing to reveal “any” or “all” abnormalities that may exist without any specific indication and without limit.

As Part I explains, the three tests typically requested — CMA, WES, and WGS — invade privacy and produce information at very different scales. Make the defense specify exactly what testing they want and why. The broader the request, the harder it should be to justify.

WGS is the easiest to challenge because of the sheer volume of information it produces and the certainty that much of it will have nothing to do with the litigation. WES is the most common defense request and is what most reported decisions involve. Most birth injury defense requests are non-specific, covering “any” or “all” genetic abnormalities, without identifying what the defense is actually looking for. That is the structural defect to attack: a request without a target is, by definition, a fishing expedition. Force them to name the test, name the gene set, and explain why.

If the court is going to order testing, your fallback position is to limit it. Insist that any ordered testing be confined to the specific disorders the defense has actually articulated as potentially relevant in your client's particular case — and no further. We will see in Tip 5 that the only published authority granting compelled WES did so precisely because the defense had identified specific candidate disorders. Hold them to that standard, or hold them to a narrower test (e.g., a targeted panel, CMA only).

⁶ *Schlagenhauf*, 379 U.S. 104, 118 (1964).

Tip 4: Make the Defense Produce Competent 702 Expert Testimony

This is the heart of it. Expert testimony is essential to show good cause for compelled genetic testing of this kind. In the absence of a competent showing based on expert testimony demonstrating a reliable scientific basis for the testing, as opposed to a conclusory declaration, a court must conclude that the movant has not shown good cause.

“In the absence of a competent showing based on expert testimony demonstrating that there is a reliable scientific basis for the genetic testing, as opposed to a conclusory declaration, the Court [must conclude] that Defendants have not made a sufficient showing of good cause to support the request for genetic testing.” *In re 3M Combat Arms Earplug Products Liability Litigation*, 2021 U.S. Dist. LEXIS 226536, at *12 (N.D. Fla. Nov. 24, 2021).

The point is not academic. In a recent case we handled, the defense submitted **no** expert affidavit, declaration, report, or sworn testimony at all. They asked the court to rule on the pleadings and argument of counsel alone, and the court called the absence of expert support dispositive.

Even when the defense *does* come forward with expert support, that is not automatically the end of the inquiry. A court may still find that a reliable basis for the testing has not been established. See *Fisher v. Winding Waters Clinic*, 2017 U.S. Dist. LEXIS 19691 (D. Or. Feb. 13, 2017) (wherein the court requested that the defense experts respond to specific questions that the court had regarding their opinions and ultimately found their bases lacking). Do not concede the motion just because an affidavit shows up. Scrutinize whether the expert's basis is actually reliable and actually specific to your client.

It is not enough that the defense produces *an* expert who says genetic testing should be done. The opinion has to be one that the court could actually admit. Under Rule 702, the proffered testimony must rest on sufficient facts or data, be the product of reliable principles and methods, and reflect a reliable application of those methods to the facts of the case. A defense expert who cannot identify what specific condition is suspected, what data supports that suspicion, or how the proposed sequencing would reliably confirm or exclude it has not offered a 702-qualified opinion. They have merely offered a conclusory declaration in expert clothing. Press the court to actually conduct the gatekeeping analysis. If the defense will not give the court the material it needs to perform that analysis, including the expert's identity, qualifications, and stated basis, the court cannot find good cause.

Further, experts cannot testify to something in court that differs from what they do in their normal professional life. This is an area that we don't see pushed in combatting motions for genetic testing as often as perhaps it should. If a physician, or a geneticist in particular, would not order testing for a patient in their practice, it follows that the only reason testing is recommended in the litigation is to push a legal theory or defense.

A particular trap to watch for is the *non-geneticist* defense expert. The defense will often try to slip a Rule 702 affidavit in from an OB-GYN, a neonatologist, or a pediatric neurologist who “thinks genetic testing should be considered.” That witness has the wrong specialty. Genetic indication and genetic interpretation are the province of clinical geneticists. Make the point on the record.

Tip 5: Demand a SPECIFIC Condition — and a SPECIFIC Link to Existing Findings

Even when the defense *does* produce an expert, the testimony has to do real work. It is not enough to gesture at the possibility that “something genetic” might exist. The defense must establish, with competent 702 testimony as described above, both:

1. **A specific genetic or metabolic condition** they contend is actually present — not a category, not a list of “potential” abnormalities, not “something genetic might exist.” If they contend a particular syndrome explains the injury, it is their burden to *identify that condition. -and-*
2. **A specific link between that condition and the findings actually documented in this child.** The defense expert has to connect the named syndrome to the constellation of findings in the record and explain why it is *likely present here*.

This is the line between good cause and a fishing expedition. Rule 35 does not permit a genetic fishing expedition simply because broader testing is technologically available, particularly where there is already a clear clinical basis for a non-genetic diagnosis in the record. Use that phrase. Make the defense show you the specific result they expect and the specific symptoms tied to it; if they cannot, you have a fishing expedition, and you should say so plainly.

For example, in a recent case we handled, the defense argued that genetic testing was warranted because the child was born with polydactyly, a congenital abnormality where the child has an extra digit on either the ulnar or radial portion of

the hand. The defense failed to present any expert testimony, believing that the existence of one known abnormality opened the door to testing for any additional genetic defects. However, the court pressed the defense for any scientific proof that the existence of polydactyly made it any more likely that the child had a genetic disorder that mimicked HIE, and because they could only fall back on what “might exist,” the court denied the motion.⁷

The primary case the defense often cites is *Burt v. Winona Health Services*, 2018 WL 3647230 (D. Minn. Aug. 1, 2018). In *Burt*, the district court reversed a magistrate judge's denial of the genetic testing motion and ordered whole-exome sequencing. *Burt* is bad authority for plaintiffs, but it is instructive in defining what defendants actually have to show. The court there found good cause because the experts had identified specific genetic disorders and specific conditions that “could be likely culprits” of the claimed disability; the defense in *Burt* met the high bar.⁸ The defense in most cases does not.

Treat *Burt* as the standard the defense must clear, not as a permissive precedent for compelled testing on a record short of what the court in that case required. Where the defense cannot identify named conditions, *Burt* itself cuts the other way. And even where they can, insist that the ordered testing be limited to the conditions actually articulated — not an open-ended sequencing of the child's genome.

Tip 6: Press the Constitutional and Privacy Concerns

Rule 35 is the procedural battleground, but it is not the only one. Compelled genetic testing of a

⁷ Our expert also explained why the type of polydactyly existing in the plaintiff was not the type that, in very rare situations, may accompany other genetic abnormalities.

⁸ Notably, even in *Burt* where the defense submitted numerous expert witnesses in support of their motion, and

the plaintiffs essentially agreed that testing could be appropriate, the court found the decision to be “an extremely close call.” *Id.* at *6.

child also implicates constitutional and statutory privacy protections that should be raised alongside—and woven into—the “good cause” argument. These do not displace the Rule 35 analysis; they reinforce the strict construction Rule 35 already demands, and they give the court additional reasons to deny the motion or, at a minimum, to issue a robust protective order.

Here’s how to make these arguments to the court.

First, start with the proposition that bodily integrity is a “sacred” right under longstanding U.S. Supreme Court authority.

The earliest basis is *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891), where the United States Supreme Court declared that “[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person.” Courts evaluating Rule 35 genetic testing motions have invoked *Botsford* to require strict construction of the rule, recognizing that compelled physical examination—and particularly compelled genetic analysis—diminishes that right. See *Fisher for X.S.F. v. Winding Waters Clinic, PC*, 2017 U.S. Dist. LEXIS 19691 (D. Or. Feb. 13, 2017).

Second, acknowledge “the vast amount of personal and private information unspecified genetic testing reveals.” *Rogers-Duell v. Ying-Jen Chen*, 974 N.Y.S.2d 769 (Sup. Ct. 2013). As succinctly recognized by the legislative history that led to the DNA Analysis Backlog Elimination Act (42 USC § 14135a):

The information obtainable from DNA testing surpasses any previous types of testing available. The amount of personal and private data contained in a DNA specimen provides

insights into the most personal family relationships and the most intimate workings of the human body, including the likelihood of the occurrence of over 4,000 types of genetic conditions and diseases. Genetic information pertains not only to the individual whose DNA is sampled, but also to anyone who shares that bloodline. HR Rep 106-900[I], 106th Cong, 2d. Sess, available at 2000 WL 1420163, *52.

The vast scope of information accessible by genetic testing, and its potential misuse, was also recognized by Congress when it passed the Genetic Information Nondiscrimination Act of 2008, which prohibits employers from requesting (or discriminating) based on genetic information.

Third, indicate that informational privacy—what the test reveals beyond the litigation—is a constitutional concern in its own right.

Genetic testing, and particularly whole exome sequencing, gathers far more information than is relevant to any HIE causation defense. In *Fisher v. Winding Waters Clinic*, the court found that WES “has the potential to uncover genetic predispositions to numerous conditions unrelated to [the child’s] known injuries, such as cancer, cardiac arrhythmias, neurologic disorders, and metabolic disorders,” and that this “sweeping invasion of personal integrity and privacy strongly weighs against a finding of good cause.”⁹ The *Fisher* court also recognized that the harm is not limited to disclosure — there is “an invasion of privacy in the information having been gathered, and harm in the information simply existing,” with future risks including insurance applications, subsequent court proceedings, and breaches of electronic medical records.

Fourth, point out the non-party parent problem. To properly analyze whole-exome

⁹ LEXIS 19691 at *17-18 (citing *Schlagenhauf*, 379 U.S. at 12 (criticizing proposed examinations for being excessively “wide-ranging”)).

sequencing of a child, it requires comparing the genetic sequencing of the parents, who in most birth injury cases are non-parties or appear only in a representative capacity as the child's legal guardian or next of kin. This means that a defendant's request for whole-exome sequencing almost certainly inherently is asking for the court to compel the child's non-party parents to also undergo genetic testing.

Courts have almost uniformly held that Rule 35 does *not* authorize compelled examination of non-parties. In *Young v. United States*, 311 F.R.D. 117 (M.D. Fla. 2015), the district court held that it lacked authority to order non-party parents to submit to genetic testing —and rejected the argument that a mother suing in a representative capacity could be compelled as a “party.” The district court also rejected a proportionality analysis as “counter to the express language of Rule 35.” *Fisher* reached the same conclusion.

Fifth, research if your state has any additional privacy protections for genetic information. Georgia, for instance, has a genetic privacy statute that reinforces the analysis. In Georgia state court proceedings, O.C.G.A. § 33-54-1 declares that “genetic information is the unique property of the individual tested” and that genetic information is subject to abuse if disclosed without consent. O.C.G.A. § 33-54-3(a) further provides that genetic testing “may only be

conducted to obtain information for therapeutic or diagnostic purposes” and “may not be conducted without the prior written consent of the person to be tested,” and that information derived from such testing is “confidential and privileged.” The statute is primarily directed at the insurance context, but its declaration of genetic information as the “unique property” of the individual, and its consent requirement, articulate a Georgia public policy that should inform a state court's good-cause analysis under O.C.G.A. § 9-11-35. In federal court, the same statutory policy may inform the good-cause analysis under Federal Rule 35 and supports a protective order under Federal Rule 26(c).

If the court is inclined to order *some* testing, build a protective-order proposal that ties testing to the specific conditions identified by the defense expert, restricts use to this litigation, prohibits disclosure to insurers and third parties, requires destruction of biological samples after testing, and seals results from the public record.¹⁰

Tip 7: Use Prior Normal Genetic Screening

Check the prenatal and neonatal records. It is common for the child and mother to have already undergone genetic screening, including testing conducted during pregnancy that returned normal results. Many metabolic disorders that

¹⁰ **What To Ask for in a Protective Order:** If the court is inclined to allow any genetic testing, we typically ask that the court's protective order, at a minimum: (1) identify the precise test authorized; (2) identify the specific genes, variants, or conditions to be analyzed; (3) prohibit whole-genome or whole-exome analysis beyond the court-approved scope; (4) prohibit reporting of incidental or secondary findings unrelated to the identified condition; (5) prohibit disclosure of carrier status, adult-onset disease risks, ancestry, paternity, or unrelated familial information; (6) limit use of the results to the pending litigation only; (7) prohibit disclosure to insurers, employers, schools, government agencies, or third parties; (8) require all

biological samples to be destroyed after testing; (9) require all raw sequencing data to be destroyed or returned at the conclusion of litigation; (10) require the results to be filed under seal if referenced in court filings; (11) limit access to counsel, retained experts, and the court; (12) prohibit reanalysis of the genetic data without further court order; and (13) preserve plaintiffs' right to challenge admissibility, reliability, relevance, and causation opinions arising from the testing. This fallback position matters. The goal is to defeat the motion. But if the court is inclined to grant some relief, the next goal is to prevent “some testing” from becoming unrestricted access to the child's genome.

could mimic HIE (e.g., MSUD, organic acidemias, fatty acid oxidation disorders, urea cycle disorders) are included in standard newborn screening panels and would be detected on routine NBS.

If negative results already exist in the record, the defense bears the burden of showing that the prior testing was inadequate, improperly performed, or incomplete in some medically meaningful way. Put the prior normal screening in front of the court and make the defense explain, through their expert, why it was insufficient. They usually cannot.

Tip 8: Work Up the Genetics Yourself

Here is the part that should change how you build the case in chief, not just how you respond to a motion.

Seasoned birth injury lawyers already know not to leave neuroradiology to the defense: you retain your own pediatric neuroradiologist to read the MRI and explain the timing and pattern of injury. You already know not to leave the placenta to the defense: you retain your own placental pathologist to address chorioamnionitis, thrombosis, maturation, and the alternative-causation theories the defense will build from the slides. Genetics is now a third discipline that demands the same treatment.

The strongest plaintiff responses to these motions do not simply argue that the defense failed to meet its burden. They come forward affirmatively with a sworn affidavit from a qualified clinical geneticist who opines that the clinical presentation is consistent with severe HIE, that no genetic syndrome is suspected, and that further sequencing is not medically indicated. Further, it should address, condition by condition, each potential genetic disorder the defense has floated, explaining why none is likely given the

child's presentation at birth and the physical features such children exhibit that this child does not. When the Plaintiff expert affidavit is the *only* expert testimony before the court, the court is generally required to accept it, and it becomes dispositive.

The lesson: retain your own geneticist early. Have that expert review the records, the prenatal and neonatal screening, the dysmorphism exam, and the family history, and produce an affidavit affirmatively explaining why the presentation is consistent with the HIE diagnoses, and why a genetic etiology is not indicated. Do not wait for the Rule 35 motion to go looking for an expert to challenge the motion.

Tip 9: Read The Cited Studies – Don't take the Defense's Word for What They Say

The defense bar has built this “genetic defense” theory primarily on a handful of studies. They are real, and they are worth understanding. But they are also routinely overread.

A frequently cited article, Bruun et al. (2018), *Genetics in Medicine*, for instance, cites that 36% of the tested newborns with neonatal encephalopathy had genetic abnormalities. The number the defense bar rarely quotes is the inclusion criteria: the study specifically excluded any newborn with “a sentinel hypoxic event occurring immediately before or during labor” and required “no history of perinatal asphyxia.” The cohort excluded the population in which your intrapartum-HIE case sits.

Other studies the defense leans on suffer from the same problem:

* **Parobek et al. (2024), *Clinical Genetics***²¹ —

a retrospective review of 24 neonates clinically diagnosed with HIE, reporting that 6 of 24 (25%) received a genetic diagnosis. Patients were excluded if neuroimaging “suggested postnatal hypoxic-ischemic injury.” The authors framed the hypothesis as some infants with HIE have genetic disorders that *resemble* encephalopathy — they were studying mimics, not causes. The sample is only twenty-four children.

* **The cerebral palsy studies** — Moreno-De-Luca, *JAMA* (2021); McMichael, *Molecular Psychiatry* (2015); Chopra, *Annals of Clinical and Translational Neurology* (2022); Wang, *Nature Medicine* (2024). Reported yields range from roughly 11% to 32%. The cohorts were drawn largely from genetics clinics — meaning children with no identifiable perinatal insult, family history concerns, or dysmorphic features who had been referred for genetic workup. They are not representative of children with documented intrapartum HIE.

Fairly read, the literature supports this: Yes, a small subset of children labeled HIE or CP carry pathogenic genetic variants. But usually those are the cryptogenic cases, the children without sentinel events, without acidotic cord gases, without dysmorphic features, without a progressive course. The studies were designed to find diagnoses in *unexplained* cases. They are not a license to retroactively explain away the ones already explained.

So take a look at the fine print. Pull the studies the defense relies on, read the inclusion and exclusion criteria, and check whether the cohort actually resembles your client. More often than not, it does not — and that is a point your geneticist can drive home in an affidavit, and your cross-examination can drive home at deposition.

Tip 10: Reference Therapeutic Cooling Exclusion Criteria

Published protocols for therapeutic hypothermia (cooling) explicitly screen for metabolic conditions as relative exclusions — meaning neonatologists are already considering this differential at the time of admission. If cooling was initiated, it implies the clinical team evaluated and did not identify an obvious metabolic alternative.

Tip 11: Emphasize the Post-Hoc Rationalization for the Testing

Genetic testing ordered years after injury, after review of the medical record, and after proof of negligence, is subject to selection bias. Because of the significant privacy issues involved in testing of this nature, even where testing is done for legitimate medical purposes, there are limitations imposed by ACMG to protect the rights of patients and their families. It follows that testing done in the context of litigation should be no less restricted. Demonstrating that the testing is being requested solely as a litigation tactic, rather than for any accepted medical purpose (diagnosis, treatment, public health) may support your argument that good cause has not been sufficiently demonstrated.

In this regard, we find it helpful to send discovery requesting information about the defendants’ use of genetic testing outside of litigation. Request policies or procedures governing the genetic testing of newborns diagnosed with HIE; get the data on how often genetic testing is ordered for newborns diagnosed with HIE; and have them identify every geneticist

²¹ <https://pubmed.ncbi.nlm.nih.gov/38545656/>.

within its organization and the identity of every lab used for genetic testing of neonates at their institution. If they don't have a geneticist, you can argue it is not something that they focus on in the real world of patient care. If they do have a geneticist on staff, and that person has not supported the request for the testing, it will be very telling. And, of course, get the defense to admit that no provider charged with the responsibility of evaluating and/or treating the plaintiff child ordered the type of genetic testing requested in the Rule 35 motion or even suspected a genetic cause for the child's neurological injuries.

That said, we have to acknowledge that some courts are going to grant motions for genetic testing, and the results may be problematic, if only because they muddy the water and create confusion for the jury. In situations where you have to deal with tests that produce something that the defense can hang their causation hat on, it's important to let the jury know that the testing was not requested to find an answer or provide the child with proper treatment, but to find an excuse. The Bottom Line

The "it was genetic" defense is not going away. As sequencing becomes cheaper and more routine, defendants will keep reaching for it – because it is a powerful distraction and because the demand for testing itself imposes costs, delays, and an unsettling intrusion on a child and her family.

But the law has not changed to accommodate the trend. Rule 35 still treats a compelled examination as exceptional, still places the burden squarely on the movant, and still demands a specific, expert-supported showing of good cause for the particular testing sought.

These children forever carry the consequences of what happened in the delivery room. The genetic

fishing expedition is an effort to shift the focus away from that.

Our job is to keep it there.

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