

2nd Circ. Tylenol MDL Ruling Clarifies Court Gatekeeper Role

By **Wayne Fang and Andrew Brown** (September 16, 2026)

On July 13, in a precedential opinion, the U.S. Court of Appeals for the Second Circuit weighed in on the ongoing debate over how closely a district court may or should scrutinize a qualified expert's opinions under Rule 702 of the Federal Rules of Evidence as amended in 2023, and the U.S. Supreme Court's 1993 decision in *Daubert v. Merrell Dow Pharmaceuticals Inc.*

In *Rutledge v. Walgreen Co.*, arising from a multidistrict litigation concerning the alleged causal relationship between prenatal acetaminophen use and attention-deficit/hyperactivity disorder and/or autism spectrum disorder, the Second Circuit sought to limit overzealous gatekeeping. It directed courts to "strike a middle-ground" between "the principle that a district court must take a hard look at the experts' applications of accepted methods" and the principle that a "court cannot decide a *Daubert* motion based on its own judgment of an expert's persuasiveness."^[1]

The Second Circuit held that the district court abused its discretion in excluding three of the plaintiffs' experts, whose testimony was consistent with methodologies actually employed in their respective fields. In doing so, the circuit court found that the district court improperly substituted its own understanding of epidemiology for that of the scientists and excluded opinions that fell within the bounds of legitimate scientific debate.

Rutledge thus confirms that the 2023 amendment to Rule 702 did not represent a sea change in the governing expert admissibility standards, but clarifies and cautions that the district court's gatekeeping role is, and always has been, to shield the jury from expert testimony that is outside the boundaries of legitimate scientific discourse. It is not, however, to decide which points in any given scientific debate are more persuasive.

Rutledge is unlikely to be the final word in this hotly contested debate over where to draw the line between gatekeeper and decision-maker. Indeed, on Sept. 10, several defendants **urged** the Second Circuit to revisit its decision, arguing that the court had effectively nullified the 2023 amendment to Rule 702 and improperly restricted the district court's gatekeeping role. That determination remains pending.

The 2023 Amendment to Rule 702

As the Advisory Committee on Evidence Rules explained, in the years leading up to the amendment, many courts had erroneously "held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility."^[2]

Effective Dec. 1, 2023, Rule 702 was "amended to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule."^[3]



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The rule was also "amended to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." [4]

Difficult Terrain to Navigate

Both before and after the 2023 amendment, trial courts have struggled to determine how rigorously to scrutinize expert testimony, particularly when evaluating testimony concerning controversial or highly technical scientific issues.

During an Oct. 10, 2025, oral argument in *In re: Zantac (Ranitidine) Products Liability* Litigation before the U.S. Court of Appeals for the Eleventh Circuit, U.S. Circuit Judge Adalberto Jordan observed that "the problem is that there's been too much ink spilled" in this area of the law, and described it as "difficult terrain to navigate." [5] Judge Jordan later characterized the line between gatekeeper and decision-maker as "unintelligible." [6]

At oral arguments in *Rutledge*, U.S. Circuit Judge Gerard E. Lynch similarly observed that, as a judge, "you're not supposed to play scientist, but you are supposed to take a hard look at what the scientists say." [7] He acknowledged that "the poor district judge has to walk a certain line there and hopefully we might be able to give some guidance there as to how to walk that line." [8]

Rutledge represents the Second Circuit's guidance on this issue.

Reining In Overzealous Gatekeeping

In *Rutledge* and its companion case, *Phippen v. Walgreen Co.*, children, parents and guardians asserted state law failure-to-warn claims against pharmaceutical companies, pharmacies and retailers, alleging that prenatal ingestion of acetaminophen, the active ingredient in Tylenol and its generic equivalents, caused them or their children to develop ADHD and/or ASD. [9]

The *Rutledge* plaintiffs relied on five experts to establish a causal link. The U.S. District Court for the Southern District of New York excluded the testimony of all five experts as unreliable, reasoning that "the state of scientific evidence on prenatal use of acetaminophen presents a challenge for any expert witness offering the opinion that such use causes ADHD and ASD," and that "there is no generally accepted scientific conclusion that in utero exposure to acetaminophen causes either" condition. [10]

After emphasizing that it was not deciding whether acetaminophen in fact causes ADHD or ASD, the Second Circuit held that the district court overstepped its gatekeeping role by excluding three of the plaintiffs' experts.

The appellate court found that these "experts offered opinions that comport with methodologies applied by other scientists in their fields, and constitute acceptable interpretations of scientific evidence where scientists may, and in fact do, disagree on the ultimate answer to the causal question that they are assessing." [11]

The Second Circuit's analysis focused primarily on Dr. Andrea Baccarelli, an epidemiologist, physician and dean of the Harvard T.H. Chan School of Public Health. Baccarelli performed a Bradford Hill analysis, a widely used method for assessing whether an observed association is causal in nature, and concluded that the available epidemiological evidence supports a

finding of causality between prenatal acetaminophen exposure and ADHD and ASD.

The Second Circuit found his methodology and its application sufficiently reliable for a jury to consider, reasoning that many of the district court's criticisms went to the persuasiveness of Baccarelli's conclusions, rather than the admissibility of his testimony.

One example illustrates the line the court drew. Baccarelli evaluated ADHD and ASD together in a single Bradford Hill analysis rather than performing separate analyses for each condition. The district court found that approach unreliable, largely because ADHD and ASD have different diagnostic criteria.

The Second Circuit disagreed, concluding that Baccarelli adequately explained his methodological choice and that epidemiologists routinely employ the same methodology outside the context of litigation.

Drawing a sharp distinction between admissibility and persuasiveness, the Second Circuit explained that "we do not conclude that we think the structure Baccarelli employed for his Bradford Hill analysis is the best one, nor do we have any prediction, one way or another, about whether a jury will find it persuasive." [12]

In the court's view, Baccarelli's "single, multiple-outcomes analysis may well prove unconvincing to a jury for precisely the reasons that the district court identifies, but that does not render the expert opinion excludable for the purposes of Rule 702." [13]

The Second Circuit further rejected the district court's accusation that Baccarelli engaged in cherry-picking — that is, selectively relying on evidence supporting a particular position while ignoring or discounting contrary evidence.

"It is not cherry-picking," the court explained, "for an expert to prefer one study to another when he offers a coherent, scientifically plausible reason for the preference." [14]

Practical Takeaways

Rutledge is one of the first federal appellate decisions since Rule 702's 2023 amendment to thoroughly address the question of when a court crosses the line from gatekeeper to scientific arbiter. The court sought to "strike a middle-ground" and to moderate a trend toward increasingly rigorous Rule 702 scrutiny.

Although binding only within the Second Circuit — Connecticut, New York and Vermont — Rutledge will likely influence how courts across the country discharge their gatekeeping role under Rule 702 and Daubert.

Under Rutledge, experts who offer controversial or even unpersuasive opinions may nevertheless survive a Rule 702 challenge if they: (1) apply a reliable methodology in a manner consistent with that employed by others in the relevant field, (2) fairly consider the relevant body of evidence without ignoring or misrepresenting contrary evidence, and (3) provide reasonable, scientifically or technically grounded explanations for their conclusions.

Practitioners and clients should keep these principles in mind when selecting experts, conducting expert discovery, defending expert testimony and challenging an opposing expert.

Specifically, credentials alone are not enough when selecting an expert. Counsel should

determine whether the expert employs a generally accepted methodology or, at the very least, a reliable method that has been used by other professionals in the expert's field.

This may require investigating the expert's litigation history, including prior exclusions on reliability grounds, and researching how courts or the relevant scientific community have treated the expert's chosen method.

Particular care should be taken when an expert intends to employ a novel methodology or apply an established methodology in a novel way, as courts typically scrutinize such approaches more closely than established methodologies applied in their usual manner.

Counsel should also ensure that the expert has identified and engaged with the complete body of relevant evidence underlying their opinions, and should work with the expert to develop a record sufficient to support the expert's application of the methodology and resulting opinions.

Experts, especially those advancing controversial opinions, should be prepared to explain — both in their reports and at deposition — how they applied their methodology, including any major methodological choices, assumptions or extrapolations, and how the evidence supports each conclusion. Importantly, they must also fairly confront contrary evidence and provide a sufficient explanation for distinguishing or discounting it.

Parties challenging expert testimony on reliability grounds, meanwhile, should focus on genuine defects in the expert's methodology or its application, rather than merely attacking the persuasiveness of the expert's conclusions.

Although there may be tactical reasons to argue that an expert's opinions are unpersuasive, the strongest challenges under Rule 702 identify departures from accepted practice, omitted analytical steps, selective or inaccurate treatment of contrary evidence, or assumptions and extrapolations that extend beyond what the underlying facts and methodology can reliably support.

As Rutledge counsels, exclusions grounded in methodological defects, rather than disagreements over persuasiveness, are more likely to withstand appellate review, reducing the risk of reversal and costly relitigation years later.

While Rutledge does not end the debate over where to draw the line between gatekeeper and decision-maker, it provides practitioners and courts with guidance for navigating this difficult terrain. Ultimately, Rutledge preserves meaningful gatekeeping while making clear that judges may not resolve legitimate scientific disputes themselves.

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[1] *Rutledge v. Walgreen Co.*, 182 F.4th 168, 193 n.25 (2d Cir. 2026).

[2] Fed. R. Evid. 702 Advisory Committee's note to the 2023 amendment.

[3] Id. (citing Fed. R. Evid. 104(a)).

[4] Id.

[5] Audio Recording of Oral Argument at 18:36–19:30, In re Zantac (Ranitidine) Prods. Liab. Litig., No. 21-12618 (11th Cir. Oct. 10, 2025).

[6] Id. at 39:22–39:56.

[7] Audio Recording of Oral Argument at 19:57–20:35, Rutledge v. Walgreen Co., Nos. 24-916-cv(L), 24-1121(Con), 24-2360(Con), 24-2594-cv (2d Cir. Nov. 17, 2025).

[8] Id.

[9] This article does not separately address Phippen, because the Second Circuit vacated and remanded without deciding the admissibility of Dr. Ness' testimony.

[10] In re Acetaminophen—ASD-ADHD Prods. Liab. Litig., 707 F. Supp. 3d 309, 333–34 (S.D.N.Y. 2023).

[11] Rutledge, 182 F.4th at 175.

[12] Id. at 188.

[13] Id.

[14] Id. at 191.