

**No. 23-2226**

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United States Court of Appeals  
for the Federal Circuit

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Mark A. Barry,  
*Plaintiff-Appellant,*

v.

DePuy Synthes Companies,  
*Defendant,*

DePuy Synthes Sales, Inc., trading as DePuy Synthes Spine,  
Medical Device Services, Inc, DePuy Synthes Products, Inc.  
*Defendants-Appellees.*

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On Appeal from the United States District Court for the Eastern  
District of Pennsylvania in No. 2:17-cv-03003-PD,  
the Hon. Paul S. Diamond

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**CORRECTED BRIEF OF THE HIGH TECH INVENTORS  
ALLIANCE AND THE SOFTWARE & INFORMATION INDUSTRY  
ASSOCIATION IN SUPPORT OF DEPUY SYNTHES AND  
THE PETITION FOR REHEARING**

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April 8, 2026

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## **CERTIFICATE OF INTEREST**

Pursuant to Federal Circuit Rules 29(a) and 47.4, counsel for amici certifies that:

7. The full names of the parties that I represent are the High Tech Inventors Alliance and the Software & Information Industry Association
8. There are no real parties in interest of parties that I represent
9. There are no parent corporations or publicly held companies that own ten percent or more of the stock of the parties that I represent
10. No other law firms, partners, or associates who have not entered an appearance in this appeal either appeared for the parties that I represent in the originating court or are expected to so appear in this Court
11. I do not know of any case in this or any other court or agency that will directly affect or be directly affected by this Court's decision in this case
12. No disclosure regarding organizational victims in criminal cases or debtors or trustees in bankruptcy cases is required under Fed. R. App. P. 26.1(b) or (c).

April 8, 2026

/s/ Joseph Matal

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## **INTEREST OF AMICI CURIAE**

The High Tech Inventors Alliance (HTIA) represents leading technology providers and includes some of the most innovative companies in the world. HTIA's member companies are some of the world's largest funders of research and development, investing more than \$165 billion in these activities annually. They are also some of the world's largest patent owners and have collectively been granted nearly 350,000 patents.

The Software & Information Industry Association (SIIA) is a global trade association representing nearly 400 firms involved in the business of information. Through its divisions, events and advocacy, SIIA engages industry leaders and policymakers to ensure a vibrant information ecosystem: one that fosters creation, dissemination and productive use. SIIA and its members work to proactively address issues and challenges that impact their industry segments with the goal of driving innovation and growth of the information economy.

Amici's members are frequent targets of patent assertions by parties that do not make or sell any products and thus lack a real-world basis for calculating damages; these plaintiffs instead frequently rely on various statistical models to gauge a reasonable

royalty. Amici have an abiding interest in ensuring that such analyses are reliable and are based on sound statistical principles.<sup>1</sup>

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<sup>1</sup> No counsel for any party wrote any part of this brief. No party other than amici curiae's members contributed money that was intended to fund the preparation or submission of this brief. This brief is accompanied by a motion seeking leave to file.

## INTRODUCTION

The district court excluded Dr. Neal’s statistical projections because they were not based on a randomly-selected, representative sample and because the response rate to his questions fell far below acceptable levels. As the body of this brief seeks to demonstrate, the principles that the district applied have been understood to be fundamental to a reliable statistical analysis since the middle of the twentieth century.

The panel decision, by prohibiting courts from enforcing these rules, would allow expert witnesses to use arbitrarily assembled, non-representative samples with unreliably low response rates. Such an approach would inevitably enable the manipulation of data. In this case, for example, Dr. Neal’s disproportionate reliance on the Scoliosis Research Society—a group whose members can be expected to perform more spinal surgeries than the norm—likely distorted his results.

The panel decision would make statistical projections in patent cases into a *Daubert*-free zone in which even the most fantastical numbers can be presented to a jury under the guise of “expert analysis.” The decision breaches a wide gap in the protections against meretricious expert testimony created by Federal Rule of

Evidence 702 and this Court's decision in *EcoFactor v. Google*, 137 F.4th 1333 (Fed. Cir. 2025).

## ARGUMENT

### **I. Dr. Neal’s study violates fundamental rules of statistical analysis.**

To project how frequently the approximately 50,000 spine surgeons in the United States used the claimed method, Dr. Neal sent an email inquiry to about 4,000 surgeons. Dr. Neal assembled this admittedly non-random sample from commercial mailing lists, web searches, and a list compiled by Dr. Barry’s counsel of 522 members of the Scoliosis Research Society, a professional association whose members dedicate at least 20% of their practice to treating spinal deformities. From these 4,000 mail inquiries, Dr. Neal obtained 164 replies—a response rate of 4%. This 164-surgeon sample was used by Dr. Neal to project that the spine surgeons in the United States had performed 610,000 spinal deformity surgeries.

“The proponent [of a statistical survey] must show that [it] was conducted in accordance with generally accepted survey principles and that the results were used in a statistically correct manner.” *Keith v. Volpe*, 858 F.2d 467, 480 (9th Cir. 1988); *Baumholser v. Amax Coal Co.*, 630 F.2d 550, 552 (7th Cir. 1980) (same). “Statistical calculations performed on data . . . are not probative of anything

without support from an underlying statistical theory.” *Frazier v. Consolidated Rail Corp.*, 851 F.2d 1447, 1452 (D.D.C. 1988).

**A. Dr. Neal’s projections are unreliable because they are not based on a randomly-selected, representative sample.**

Modern authorities on statistics uniformly agree that in order for a sample population to serve as a reliable basis for projecting characteristics of a larger population, the sample must be *representative*—the sample must include the surveyed characteristics in the same proportions as the general population:

- “One of the most important considerations in conducting a study is to ensure that a representative sample has been taken in such a way that the sample represents the underlying population of interest.”<sup>2</sup>
- “Obviously it is of crucial importance for any statistical investigation that the characteristics of the population are reflected in the sample. If this is the case, we say that the sample is *representative*.”<sup>3</sup>

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<sup>2</sup> Mann, P., *Introductory Statistics*, 9th ed., at 25 (2016).

<sup>3</sup> Sandblom, C.L., *Elementary Statistics for Business and Economics*, 1st ed., at 121 (2019).

- “A good sample is one that is representative of the population it came from. That is, a representative sample resembles the population that it came from on all characteristics . . . except total size. A representative sample is like the population except that it is smaller.”<sup>4</sup>

Of course, unless one conducts a census of the full population, “we can never know with any certainty if the sample does or does not, in fact, represent the population.”<sup>5</sup> The way that statistical analysis overcomes this problem is by drawing a *random sample* from the full population—a sample in which “all units have a positive probability of being selected.”<sup>6</sup>

“[R]andom selection is a very powerful tool. It is the aspect of the survey process that allows researchers to generalize findings from the sample back to the population from which it was drawn.”<sup>7</sup> With random samples—also referred to as “probability samples”—

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<sup>4</sup> Johnson, B. and Christensen, L., *Educational Research.*, 8th ed., at 259 (2024).

<sup>5</sup> Ruel, E. et al., *The Practice of Survey Research*, 1st ed., at 149 (2015).

<sup>6</sup> Esteban-Bravo, M. and Vidal-Sanz, J., *Marketing Research Methods*, Cambridge University Press, at 664 (2020).

<sup>7</sup> Ruel, *supra* n.5, at 124.

“researchers [can] use formulas to calculate the sample size required, given target levels of acceptable error . . . and levels of confidence.”<sup>8</sup>

One principle on which all modern authorities agree is that for a sample to be able to project the characteristics of a larger population with any statistical rigor—with known confidence intervals and margins of error—the sample *must be randomly selected*:

- “When the sample does represent the population, we say the sample is generalizable. Under this condition, any statistically significant findings about the sample can be inferred to the population from which it was drawn. *Only a random sample or probability sample allows us to do this.*”<sup>9</sup>
- “[T]he inference from sample to population relies on the sample having been generated by a known probabilistic mechanism.

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<sup>8</sup> McDaniel, C. and Gates, R., *Marketing Research*, 12th ed., at 106 (2020).

<sup>9</sup> Ruel, *supra* n.5, at 125 (emphasis added); *see also id.* at 133 (“A sample can truly be deemed representative only if the way in which the sample has been chosen was through some sort of random method, since random sampling minimizes the likelihood of bias. It is important to note that the mechanism for selection must be truly random.”).

For this reason, *serious social and economic surveys employ probability sampling methods.*<sup>10</sup>

- Frequently, we see sample size and/or sampling error calculations done for samples that are clearly not random samples. This is totally inappropriate and, really, deceptive. The fact is that if we have a sample that does not meet the requirements of a random sample, then the level of sampling error cannot be calculated and any calculations related to sampling error or sample size are totally inappropriate. It does not matter how big the sample is even if it is in the hundreds of thousands or millions; *if it is not a random sample, then these calculations are not valid.*<sup>11</sup>

Conversely, the same authorities agree that nonprobability samples—ones that are not randomly collected from the full population—are *not* a reliable basis for projecting the characteristics of a larger population:

- “Non-probabilistic sampling methods do not allow a bias correction, and they are completely inappropriate for

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<sup>10</sup> Engel, U. et al., *Improving Survey Methods*, at 319 (2014) (emphasis added).

<sup>11</sup> McDaniel, *supra* n.8, at 113 (emphasis added).

quantitative research. In these methods we do not know the probability that some specific element from the population is selected . . . , and some individuals could be excluded a priori. . . . Any estimator computed from a sample based on non-probabilistic methods will be biased, and they are also inconsistent. Increasing the sample size, we do not get better results. More importantly, the researcher cannot correct the bias implicit in this type of sample. Therefore, *the statistical sample results cannot be extrapolated to the population.*<sup>12</sup>

- “When researchers use non-probability sampling procedures, the prevalence of the participants (with all their inherent characteristics) in the population is not taken into consideration and so *the probability of an element being sampled from the population cannot be established.* These types of sampling procedures often result in samples that are not representative and may be systematically different from the population. . . . [C]onsidering the importance of external

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<sup>12</sup> Esteban-Bravo, *supra* n.6, at 664 (emphasis added); see also Daniel, J., *Sampling Essentials*, 1st ed., at 69 (2011) (“Nonprobability sampling lacks a mathematical basis for estimating the margin of error of estimates generated via the sample.”).

validity in the quantitative tradition, probability-based procedures are considered the gold standard.”<sup>13</sup>

It is undisputed that Dr. Neal did not rely on a random or probability sample. Instead, he used a type of nonprobability sample that is known as a “convenience sample”—“a technique that allows the researcher to select any participants who are available to participate in a study, even if they are not representative of a population.”<sup>14</sup>

“Convenience sampling is the crudest form of nonrandom sampling.”<sup>15</sup> The relevant authorities warn against the use of such samples:

Extreme caution should be exercised with convenience sampling, since there is absolutely no basis upon which to conclude that the sample would in any way be representative of a larger population. Generalizations from the survey findings cannot be supported with this sampling method.<sup>16</sup>

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<sup>13</sup> Bernauer, J. and O’Dwyer, L., *Quantitative Research for the Qualitative Researcher*, 1st ed., at 78 (2013) (emphasis added).

<sup>14</sup> Pajo, B., *Introduction to Research Methods*, 2nd ed., at 123 (2022).

<sup>15</sup> Ruel, *supra* n.5, at 150.

<sup>16</sup> *Id.*; see also Engel, R. and Schutt, R., *Fundamentals of Social Work Research*, 2nd ed., at 104 (2014) (“Availability sampling often masquerades as a more rigorous form of research,” but its results “are not generalizable to other people or the broader community.”);

Statisticians condone the use of nonprobability and convenience samples only for purposes such as exploratory research or pilot programs—*not* for projecting the characteristics of the sample onto a larger population.<sup>17</sup>

Finally, because the membership in Dr. Neal’s sample was effectively determined by who opted to respond to his messages, the representativeness of the sample was further undermined by “self-selection bias—the polling bias that results from allowing subjects to choose whether to respond or not.”<sup>18</sup> As one expert has noted, “the possibility of self-selection bias that [such] polls allow is so great that they should be given no credibility whatsoever.”<sup>19</sup>

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*Competitive Edge, Inc. v. Staples, Inc.*, 763 F.Supp.2d 997, 1008 (N.D. Ill. 2010) (excluding a survey that relied on a convenience sample).

<sup>17</sup> See Pajo, *supra* n.14, at 123; Daniel, *supra* n.12, at 69; Engel, *supra* n.16, at 104.

<sup>18</sup> Battersby, M., *Is That a Fact?*, 2nd ed., Broadview Press, at 41 (2016).

<sup>19</sup> *Id.*

Statistics textbooks note that the use of nonprobability sampling was discredited by the 1948 presidential election—pollsters had relied on nonrandom quota samples to incorrectly project that Thomas Dewey would become the next President of the United States.<sup>20</sup> Here, the district court appropriately rejected Dr. Neal’s attempt to clothe his unreliable methods in the authority of statistical analysis. This Court, too, should refuse to allow patent expert witnesses to repeat the mistakes of the past.



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<sup>20</sup> See, e.g., Mann, *supra* n.2, at 13; see also *Fish v. Kobach*, 309 F.Supp.3d 1048, 1059-60 (D. Kan. 2018) (noting that “academic literature for decades has discredited [nonprobability] quotas [sampling]”).

**Dr. Neal's response rate falls far below acceptable rates.**

Dr. Neal's response rate for his survey was 4%. A response rate of about 80% is required for a statistical projection from a sample to be considered reliable:

- “The quality of a sample depends not only on its design, but also on its execution. Low cooperation rates may indicate sloppy fieldwork and lack of follow-up procedures. A frequent example of this is seen in mail surveys that use a single mailing and obtain low cooperation rates, when additional mailings could increase cooperation to the generally accepted level of about 80%.”<sup>21</sup>
- “The nonresponse rate is a strong indicator of the quality of a survey. When 60–70% of sampled items refuse participation, it is likely that the participating 40–30% of subjects have different opinions, attitudes, or behavior than the majority declining to participate.<sup>22</sup> For researchers, it is very important to keep an

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<sup>21</sup> Rossi, P. et al., *Handbook of Survey Research*, Academic Press, Inc., at 157 (2013).

<sup>22</sup> Esteban-Bravo, M., *supra* n.6, at 688.

eye on the response rate, checking that it remains high, at least no less than 80%.”<sup>23</sup>

- “[Federal agencies should] [p]lan for a nonresponse bias analysis if the expected unit response rate is below 80 percent.”<sup>24</sup>
- “Any survey stage of data collection with a unit or item response rate less than 85 percent must be evaluated for the potential magnitude of nonresponse bias before the data or any analysis using the data may be released.”<sup>25</sup>
- “The higher the response rate (the lower the nonresponse rate), potentially, the higher the quality of the data, meaning that we still assess the sample as representative of the population from which it was drawn. There is some consensus that a good response rate cutoff for maintaining representativeness is 70%. . . . If a study has too high a nonresponse rate, then the

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<sup>23</sup> *Id.* at 689.

<sup>24</sup> Office of Management and Budget, Standards and Guidelines for Statistical Surveys, Guideline 1.3.4 (2006), available at [https://unstats.un.org/unsd/dnss/docs-nqaf/USA\\_standards\\_stat\\_surveys.pdf](https://unstats.un.org/unsd/dnss/docs-nqaf/USA_standards_stat_surveys.pdf)

<sup>25</sup> National Center for Education Statistics, Statistical Standards, Standard 4-4-1, available at <https://nces.ed.gov/statprog/2012/>

representativeness of the sample is compromised, and the researcher must determine how problematic the low response rate is.”<sup>26</sup>

Dr. Neal’s 4% response rate is far below what is required for a survey to be reliable. Nor did Dr. Neal make any effort to account for non-response bias, to the extent that this is even possible when the response rate is so low. Courts exclude survey evidence under Rule 702 when a response rate is this low.<sup>27</sup> The district court was correct to do so in this case.

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<sup>26</sup> Ruel, *supra* n.5, at 162.

<sup>27</sup> See *Fish v. Kobach*, 309 F.Supp.3d at 1060 (excluding survey evidence that did not report a response rate; noting that an 80% response rate is generally required); *Albert v. Warner-Lambert Co.*, 234 F.Supp.2d 101, 106 n.6 (D. Mass. 2002) (“A response rate of less than 10 percent is well below the 50 percent response rate that is considered minimally acceptable.”).

## **CONCLUSION**

Rule 702 is meant to guard against unreliable information clouding a jury's decisionmaking. *See EcoFactor*, 137 F.4th at 1339. Yet the panel decision effectively precludes the enforcement of even the most fundamental, widely-accepted standards of statistical analysis. This Court should rehear this case en banc and affirm the district court's exclusion of Dr. Neal's testimony.

Respectfully submitted,

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Dated: April 8, 2026

## **CERTIFICATE OF COMPLIANCE**

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned counsel for amici curiae certifies that this brief:

(3) complies with the type-volume limitation of Federal Circuit Rule 40(i)(3) because it contains 2,586 words, including footnotes and excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b); and

(4) complies with the typeface and style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because this document has been prepared using Microsoft Office Word and is set in the Bookman Old Style font in a size equivalent to 14 points or larger.

Dated: April 8, 2026

/s/ Joseph Matal