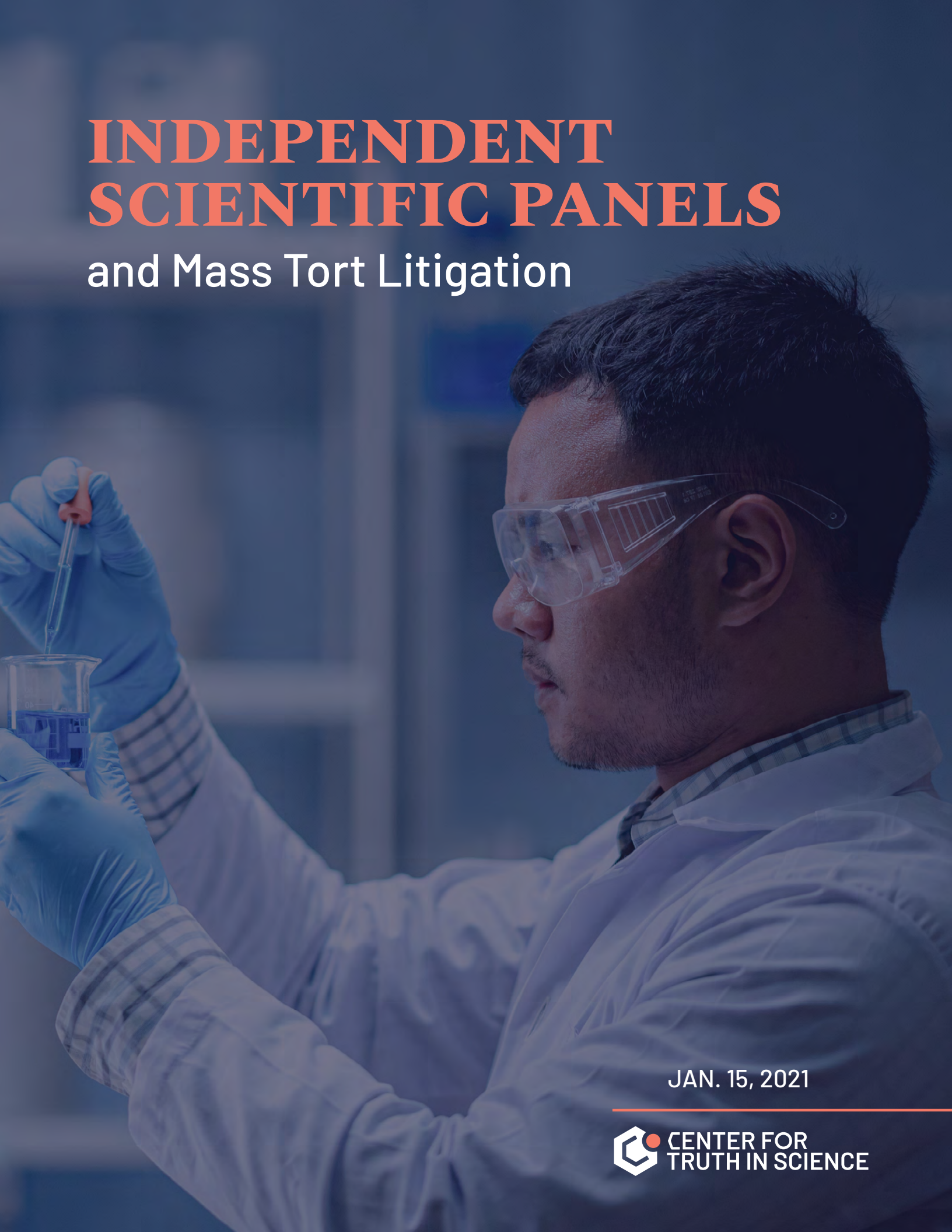
# INDEPENDENT SCIENTIFIC PANELS

## and Mass Tort Litigation



JAN. 15, 2021

CENTER FOR TRUTH IN SCIENCE

## EXECUTIVE SUMMARY

Product liability and personal injury litigation often require complex scientific data to assess the validity of plaintiff claims. In most states, the admissibility of evidence and expert testimony is governed by the Daubert Standard, which makes the presiding judge the final authority in deciding what evidence a jury is permitted to consider.

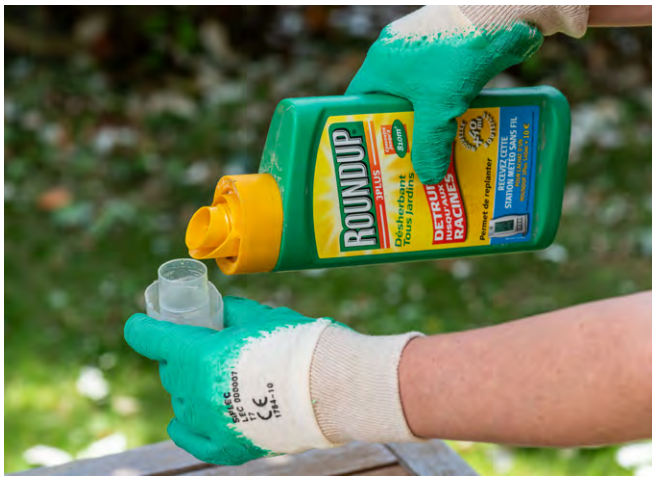
Yet, a nationwide poll conducted by Echelon Insights for the Center for Truth in Science found that two-thirds of Americans believe judges and jury members are not qualified to determine the validity of the scientific research results and expert testimony presented during a trial.[1]

The same poll found that 79 percent of Americans believe independent scientists appointed by a judge would be the most qualified to determine the validity of scientific claims as they relate to potential awards in mass tort cases. Respondents were most comfortable with scientists who are not being paid for their testimony in lawsuits about products.

***Seventy-nine percent of Americans believe independent scientists appointed by a judge would be the most qualified to determine the validity of scientific claims as they relate to potential awards in mass tort cases.***

The logic makes sense: The soundness of any scientific claim should be determined by scientists. Judges can appoint a panel of qualified scientists to determine the validity of claims before they are allowed to be introduced as evidence in tort lawsuits. However, the approach is frequently dismissed by judges as an infringement on the jury's responsibility to determine liability and their own authority to determine the admissibility of evidence.

## WHEN COURTROOMS SETTLE SCIENCE WITHOUT SCIENTISTS




Most recently, U.S. District Judge Vince Chhabria denied a proposal from both plaintiffs' attorneys and defense counsel to create such a scientific panel in the *Roundup Products Liability Litigation* (MDL No. 2741).[2] In this case, the plaintiffs' attorneys claim that glyphosate, the active chemical in the herbicide "Roundup," is carcinogenic.

The attorneys allege that exposure to the chemical causes non-Hodgkin's lymphoma, and support this claim with a single report issued in 2015 by the International Agency for Research on Cancer (IARC). The IARC's report found that glyphosate is a "probable carcinogen."[3]

However, the report largely ignored scientific evidence that didn't support glyphosate's carcinogenicity, and it was discovered a special advisor to the IARC panel that issued the report was taking money from the very mass tort firms that filed suit against glyphosate manufacturers. This report and the reputation of the IARC are now widely regarded as corrupt.[4]

Nevertheless, the corrupt report spawned thousands of tort cases, the vast majority of which are still making their way through the legal system. More than 18,000 lawsuits have been filed, costing billions of dollars in settlements.[5,6]

The lawsuits may have been settled, but the science is not. Overwhelming scientific evidence presented by multiple regulatory agencies worldwide—including reviews of current scientific literature conducted independently by the U.S. Environmental Protection Agency, the European Food Safety Authority, and the World Health Organization, of which the IARC is technically a subsidiary—have found no definitive link between glyphosate and cancer.[7]

It was on the basis of this evidence, submitted by the defense, that another federal judge permanently blocked efforts by the state of California to require cancer warnings on Roundup containers. The ruling was a victory for scientific facts over simple opinions, but the progress in that direction was quickly flustered.

Almost immediately after the ruling, Bayer Corporation elected to pay more than $10 billion to settle claims of glyphosate allegedly causing non-Hodgkin's lymphoma. This decision was *not* predicated on the scientific validity of plaintiffs' claims, but on the incalculable costs associated with litigation across thousands of court cases.[8]

The settlements allowed Bayer to define their costs, move on, and continue making a product that, arguably, benefits societies and economies around the world by reducing the cost and increasing the yield of agricultural products that feed an increasingly hungry population.

***[The] opinion that judges and juries are the proper arbiters of complicated scientific issues, often without having full understanding of all the objective data available and how it relates to the case, is the primary roadblock preventing the use of independent scientific panels to determine claim validity in tort litigation.***

The settlement included a proposed agreement between plaintiffs and defendants: both sides asked the court to appoint—and agreed to be bound by—the findings of a scientific panel that would conduct an unbiased review to evaluate association between glyphosate and cancer. In doing so, the findings of the panel would function as precedent for settling any future claims. The agreement itself would have raised the standard for all claims made in tort litigation to be more scientifically valid.

It was not to be. Judge Chhabria questioned "whether it would be constitutional (or otherwise lawful)" to delegate any issue being litigated to a panel of scientists instead of judges and juries.[9] This opinion that judges and juries are the proper arbiters of complicated scientific issues, often without having full understanding of all the objective data available and how it relates to the case, is the primary roadblock preventing the use of independent scientific panels to determine claim validity in tort litigation.

## INDEPENDENT SCIENTIFIC PANELS IN PRACTICE

Two court cases are notable for their use of scientific panels to verify claims made in mass tort litigation: *Hall v. Baxter Healthcare Corporation* and *Silicone Gel Breast Implants Products Liability Litigation* (MDL-926).

### *Hall v. Baxter Healthcare Corporation*

In 1996, Chief Judge Sam C. Pointer, Jr. remanded approximately 70 cases of breast implant litigation to the District of Oregon, which were then consolidated as a multidistrict litigation under the authority of Judge Robert E. Jones. The plaintiffs were suing breast implant manufacturers for damages for injuries they claimed were a result of their silicone gel breast implants.

According to the court documentation:

> "Among other things, the plaintiffs assert that silicone from the implants has migrated and degraded in their bodies and has caused a systemic syndrome or illness, which they generally refer to as 'atypical connective tissue disease' (ACTD). In essence, plaintiffs claim a 'unique constellation of symptoms' consisting of hundreds of symptoms commonly experienced by the general population."[10]

At the plaintiffs' request, Judge Jones met with counsel to learn about the scientific testimony both sides planned to review at trial. The defendants subsequently filed 25 motions to exclude the plaintiffs' expert testimony for establishing causation of systemic connective tissue disease.[11] Pursuant to these motions, Judge Jones scheduled an evidentiary hearing to consider the admissibility of the scientific evidence.

Given the complexity of the scientific data, Judge Jones enlisted the help of a medical school professor to identify neutral experts to determine what testimony and evidence would be allowed at trial. Experts in the fields of immunology, epidemiology, rheumatology and biochemistry were selected as "technical advisors" to Judge Jones, rather than testifying at trial in front of a jury that could be unduly prejudiced.

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The technical advisors found little scientific support for the plaintiffs' expert claims. The immunologist did not find their positions well-supported by available data or derived from conclusions in published scientific literature. The rheumatologist did not find the methodology to be scientifically valid. The biochemist concluded the chemical studies were based on appropriate methods, but that some of the work clearly required additional documentation.

The epidemiologist deemed the plaintiffs' epidemiology opinions scientifically valid, but the testimony was excluded on the basis that two of the experts' testimony was unreliable. Judge Jones found that all the reports, taken together, reached the same conclusion: scientific evidence linking silicone gel breast implants to disease was neither definitive nor reliable.

Judge Jones granted the defendants' motions to exclude the dubious "scientific evidence" proposed by the plaintiffs linking silicone gel breast implants to autoimmune disorders or atypical connective tissue disease.[12] The scientific panel employed in this lawsuit was effective, but difficult to finance. There was no existing mechanism in place to pay for the technical advisors' time and expertise:

> "The costs associated with appointing a special master and the four technical advisors totaled approximately

$76,000. Securing funds to compensate the technical advisors was problematic. Initially, at Judge Jones's request, the parties agreed to pay a total of $20,000 toward creation of the neutral panel with the understanding that they would later be reimbursed by the judiciary. Judge Jones requested federal funding because he anticipated that his advisors' reports would be useful in resolving numerous silicone gel breast implant cases pending in federal and state courts. Judge Jones's request for funding was denied by the Judicial Conference and the parties were not reimbursed for the funds they paid the technical advisors."[13]

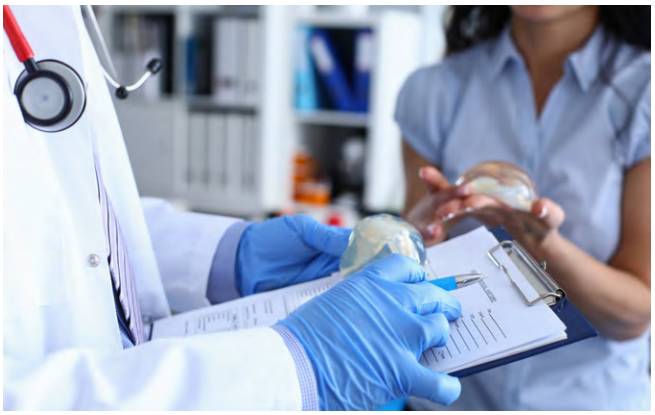
Additionally, this approach to forming the scientific panel only restricted evidence submitted to the jury at the discretion of the presiding judge. Even supposing all that evidence is scientifically valid, it imposes no obligation on either a judge or a jury to rule in favor of whatever side the evidence supports.

## *Silicone Gel Breast Implants Products Liability Litigation (MDL-926)*

In 1992, the Judicial Panel on Multidistrict Litigation transferred all pending federal court actions in which plaintiffs alleged they had been injured by silicone gel breast implants to the Northern District of Alabama.[14] Two years later, one of the defendants suggested Judge Sam Pointer, Jr. appoint a national panel of experts to advise the court on the complex issues surrounding causation.

This idea came to fruition in 1996, when Judge Pointer began remanding cases to their original courts after the multidistrict litigation pretrial proceedings. At one such hearing, a Judge Weinstein reported concerns about the validity of some of the plaintiffs' scientific claims. Judges Weinstein and Harold Baer consulted with three "special masters" to identify experts for appointment to the National Science Panel that would advise the court as expert witnesses in the litigation.

After some objections from both plaintiffs and defendants, unbiased panelists were selected in the fields of immunology, epidemiology, rheumatology, and toxicology to serve on the National Science Panel. The experts on the panel were not committed to a position regarding breast implant litigation, had not conducted existing research on silicone implant exposure, and had not previously testified in similar hearings.



Judge Pointer asked members of the panel to review scientific literature and determine if it concluded that silicone gel breast implants cause a number of diseases. His instructions also imposed restrictions on all communication with and among the panelists in an effort to prevent outside influence. The rules resulted in confusion and hurt the ability of the panelists to communicate with each other and with the authors of the research being reviewed. This made it difficult for the panel to collectively formulate a report.

In 1998, the panel members completed their report with a consensus there is no causal link between silicone breast implants and disease. The toxicologist concluded "[t]he preponderance of data from [animal] studies indicate that silicone implants do not alter incidence or severity of autoimmune disease ... the toxicologic and immunologic responses are few in number and questionable in significance."[15]

The immunologist found the majority of the studies available for analysis were inadequate to draw any conclusion and often used non-standard data analyses and concluded that women with silicone breast implants did not display a silicone-induced abnormality in cells of their immune system.

The epidemiologist found "no association between breast implants and any of the individual connective tissue diseases, all definite connective diseases combined, or the other autoimmune/rheumatic conditions." The rheumatologist reported problems with many of the studies, among them, "the same complaint appeared in more than one disease category; self-report was not verified; timing of the complaint in relation to the implant was not known; indication for the implant was ignored; and in individual studies, the number of affected women was small."[16]

After the report was completed, the legal counsel for the plaintiffs and defendants were permitted to depose the panelists. Initial depositions were transcribed by a court reporter, but not videotaped. Each side was allowed roughly three hours to conduct an examination, with one attorney from each side questioning a panel member. All panelists were allowed to be present while another panelist testified.

Videotaped trial depositions were then conducted. Counsel was required to submit a list of questions before the deposition, referring to specific pages in books and articles. One panelist argued there was no need for the depositions and the panel report should be addressed strictly on its scientific merit. She protested, "science was not served by this adversarial proceeding."[17]

Across the duration of legal proceedings, the cost of the national panel of experts was $939,983. The federal judiciary provided $733,645 to fund the selection of experts and the preparation of their report. The remaining costs included fees and expenses that occurred during the depositions and testimony and were split equally between plaintiffs and defendants.

## CONCLUSION

Sound scientific research should be the foundation of any major decisions at the intersection of science, justice, and the economy. In these cases, independent scientific panels provided neutral analysis to the courts as a tool for making well-informed decisions based on fact-based evidence.

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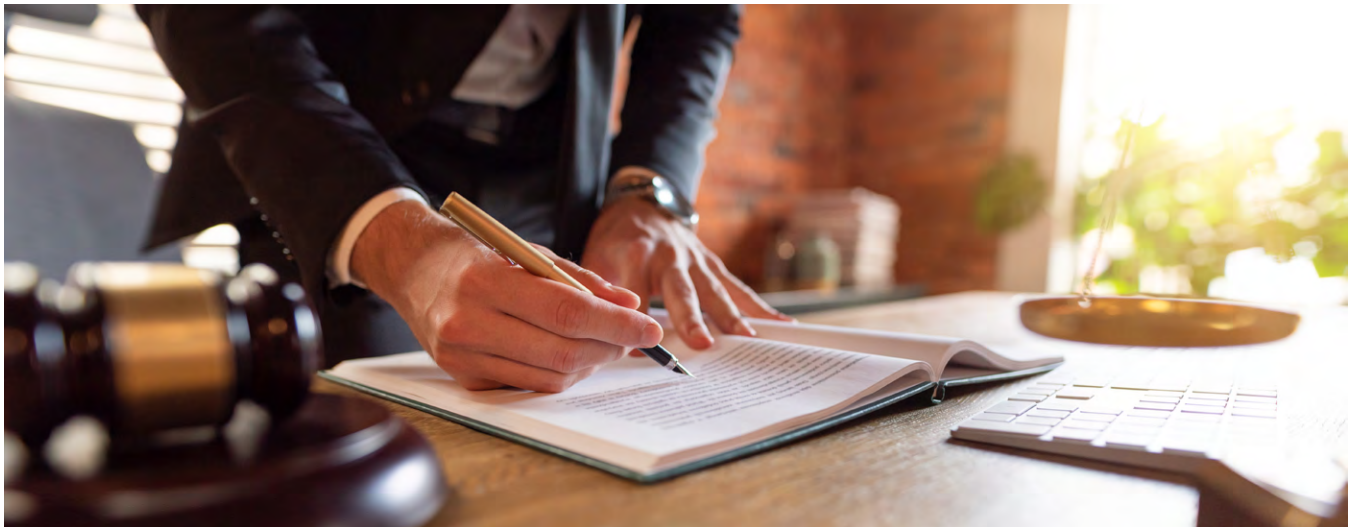
A priority for the scientific and judicial communities must be investigating how such panels could be more widely used in mass tort litigation, seeking answers to the following questions:

- What criteria should be used to select the members of independent scientific panels?
- Who should be responsible for this selection?
- What guidelines should be given to independent scientists studying each issue?
- How should the scientific evidence be presented to the court—should a judge have discretion over what is presented to a jury, or should the evidence in its entirety be provided to ensure integrity and transparency of process?



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