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THE CONSENSUS RULE: LESSONS FROM THE REGULATORY WORLD

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INTRODUCTION

THE *Daubert* test, which provides courts with guidelines on how to evaluate the reliability of scientific evidence,[1] has spawned confusion and "sub-optimal" decision-making among many judges who endeavor to apply its abstract tenets.[2] Trial judges have applied the *Daubert* factors in different, sometimes mutually inconsistent ways that may even deprive some litigants of their constitutional right to trial by jury.[3] Scientists accuse judges of playing "amateur scientist" under *Daubert*, showcasing the judiciary's limited scientific competency.[4] Attorneys, who the legal system depends on to educate factfinders, amplify the problems. Some counsel appear to avoid taking on low-budget cases that are poised to spark expensive *Daubert* challenges from opponents.[5] Other attorneys lack the expertise and resources to utilize the complex test for criminal clients who need it the most.[6] And still other attorneys capitalize on the Court's less-than-clear test by twisting district court judges (and opposing counsel) into knots during the protracted *Daubert* hearings.[7]

Yet, despite the undisputedly flawed *Daubert* opinion, there have been few promising contenders for a better approach. That is, until Edward Cheng. In his important article in the *Vanderbilt Law Review* (and forthcoming book), Cheng steps outside the *Daubert* "box" and imagines a completely new way to assess and use scientific evidence in courtrooms.[8] His approach not only reimagines what the judge's initial gatekeeping role

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1. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

2. *See, e.g.*, DAVID S. CAUDILL & LEWIS H. LARUE, NO MAGIC WAND: THE IDEALIZATION OF SCIENCE IN THE LAW (2006); Edward K. Cheng, *The Consensus Rule: A New Approach to Scientific Evidence,* 75 VAND. L. REV. 407, 422 (2022); Sophia I. Gatowski, Shirley A. Dobbin, James T. Richardson, Gerald P. Ginsburg, Mara L. Merlino & Veronica Dahir, *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-*Daubert *World*, 25 LAW & HUM. BEHAV. 433 (2001).

3. *See, e.g.*, Margaret A. Berger, *What Has a Decade of* Daubert *Wrought?,* 95 AM. J. PUB. HEALTH S107 (2005); Eric Helland, *The Role of Ideology in Judicial Evaluations of Experts*, 62 J.L. & ECON. 579 (2019).

4. *See, e.g.*, David Ozonoff, *Epistemology in the Courtroom: A Little "Knowledge" is a Dangerous Thing*, 95 AM. J. PUB. HEALTH S107 (2005).

5. *See, e.g.*, Berger, *supra* note 3.

6. *See, e.g.*, *id.*; D. Michael Risinger, *Navigating Expert Reliability: Are Criminal Standards of Certainty Being Left on the Dock?,* 64 ALB. L. REV. 99 (2000).

7. *See generally* Judge Harvey Brown, *Procedural Issues under* Daubert, 36 HOUS. L. REV. 1133 (1999) (detailing these and many other concerns).

8. Cheng, *supra* note 2.

might be, but he tackles the "expert paradox" head-on by proposing a new approach for courts to engage in scientific fact-finding in ways that extend well beyond just admissibility determinations.[9]

At least as impactful as Cheng's ability to rethink the courts' use of scientific evidence from the ground up is his proposal to pin his new evaluative metric on how the scientific community itself understands the evidence, rather than on how judges understand the philosophy of science.[10] Cheng bypasses all the abstractions and muddy thinking embodied in *Daubert* (what he calls "epistemic mistake[s]")[11] and brings the legal system back to its end goal—namely to rely on science that the scientific community itself agrees is reliable.

In Cheng's new world governed by the Consensus Rule, juries defer to the scientific community's substantive determinations about the state of the scientific research. Judges no longer wrestle with confusing *Daubert*-based inquiries into whether an expert statement is "testable," involves a documented "error rate," or inquire into whether the testimony has been adequately peer-reviewed.[12] The straightforward Consensus Rule instead simply asks what the mainstream scientific community thinks about a proposition. If a respected body of scientists agree that it is a reliable statement, those facts are established. If scientists have not reached a clear consensus, the jury decides the disputed facts based on the evidence presented.[13]

Cheng's proposal marks a substantial improvement over the *Daubert* approach. There is thus a great deal to applaud about Cheng's bright new idea. In preparing my own commentary, however, I focus less on complementary remarks and more on the remaining business of getting the Consensus Rule ready for prime time. A substantial change to how judges, juries, and attorneys process scientific evidence—heralded by Cheng's approach—will inevitably raise a few unanticipated challenges worthy of troubleshooting. Somewhat conveniently, moreover, since my own expertise lies not in evidence law but in the use of science for regulation, I am able to draw from the more than fifty years' experience of using consensus approaches in the regulatory sphere to identify a few potential challenges for the Consensus Rule that may warrant some finetuning.

My brief commentary unfolds in three sections. In the first Part, I situate the Consensus Rule (and my comments) within the larger area of science-policy studies to ground the analysis. Second, I offer several specific concerns about the Consensus Rule based on experience with the use of scientific consensus approaches in regulatory law. My Article closes

9. *See id.* at 407.

10. *See id.*

11. *Id.* at 426.

12. *See, e.g.,* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 (1993).

13. Cheng, *supra* note 2.

with preliminary suggestions for Cheng to consider as he finalizes his proposal.

I. CONCEPTUAL BACKDROP

The legal system typically encounters at least two types of challenges in integrating science into law, regardless of whether that science is used in regulation or the courtroom.[14] First, policymakers seek some assurance that the scientific information is reliable in ways that the scientific community itself finds trustworthy. Second, policymakers confront the epistemic and often complex question of where the science leaves off and the policymaking begins, an inquiry that is necessary to ensure that the scientists are not given too much discretion to decide controversial policy questions.

Taking on the first challenge first; is the scientific information or advice rigorous by scientific standards? In policy settings where science informs outcomes—for example determining acceptable levels of pollutants or chemical-based products—industries impacted by the resultant decision may sometimes find it in their interest to manipulate the scientific information to advance their own ends. The literature is in fact replete with accounts of how industry sponsors, who might be adversely impacted by incriminating research, find ways to "bend" that research to support their own preferred outcome.[15] This "bending" generally works from within science in the hopes of misleading even the scientific community itself by the subtle manipulations of the research process. Since the stakes (and economic consequences) for sponsors are often high, a great deal of effort can be invested by advocates in distorting the scientific evidence. Research reveals in fact numerous "science-for-profit" tactics deployed by these sponsors to produce ends-oriented science.[16] The strategies documented in the literature include: commissioning ends-oriented research through nondisclosure contracts; commissioning ends-oriented critiques (e.g., letters to the editor) in the same way; manipulating peer review; creating ideologically-stacked scientific consensus panels and even journals; harassing researchers who produce damning studies; exaggerating the un-

14. *See, e.g.*, Wendy Wagner, *No One Solution to the "New Demarcation Problem"?: A View from the Trenches*, 92 STUD. HIST. & PHIL. SCI. 177 (2022) (elaborating on these two challenges with citations).

15. *See, e.g.*, Tess Legg, Jenny Hatchard & Anna B. Gilmore, *The Science for Profit Model—How and Why Corporations Influence Science and the Use of Science in Policy and Practice*, 16 PLOS ONE (2021), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0253272#:~:text=The%20model%20shows%20that%20the,aspects%20of%20industry%2Dunfavourable%20science [https://perma.cc/7HTC-FG2W]; *see also* THOMAS MCGARITY & WENDY WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH (2008); DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH (2008); NAOMI ORESKES & ERIC M. CONWAY, MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING (2009).

16. *See, e.g.*, Legg, Hatchard & Gilmore, *supra* note 15; MCGARITY & WAGNER, *supra* note 15.

certainties in established scientific research as a reason to doubt consensus; and manipulating the published literature by hiring ghostwriters and publishing duplicative articles.

The mainstream scientific community has found itself on the defensive in detecting this ends-oriented corruption of research. Calls for expanded conflict disclosures, authorship forms, more critical peer review, and data sharing have arisen in the hope of assisting mainstream scientists to locate research produced in unreliable ways.[17] These challenges within science are by no means resolved, however. Indeed, if anything, the challenges involved in identifying this ends-oriented research produced by sponsors has opened a Pandora's box of related challenges within mainstream science with respect to identifying and checking other types of (non-sponsor-driven) ideological biases, such as raw ambition and confirmation bias, which also compromise research reliability.[18] The "replicability crisis," where some studies cannot be replicated in their results, adds still further fuel to the fire in showcasing the limitations of existing scientific conventions for assessing scientific reliability.[19]

The second challenge—the one that tends to receive more attention outside of science—involves identifying where the science leaves off in scientific advice and the embedded values begin.[20] The existential question—"what is science and what makes it different"—has preoccupied philosophers and historians for centuries. Much of their work concerns demarcating those features of science that add value to our understanding of the world and separating that empirical contribution from contribu-

17. *See, e.g.*, Bennett Holman & Kevin Elliott, *The Promise and Perils of Industry-Funded Science*, PHIL. COMPASS (June 2018) (describing the advantages and disadvantages of disclosing private funding for scientific research and potential avenues for progress); Marcus R. Munafo, Brian A. Nosek, Dorothy V.M. Bishop, Katherine S. Button, Christopher D. Chambers, Nathalie Percie du Sert, Uri Simonsohn, Eric-Jan Wagenmakers, Jennifer J. Ware & John P.A. loannidis, *A Manifesto for Reproducible Science*, 1 NATURE HUM. BEHAV. 1, 1–3 (2017) (arguing for the greater adoption of key measures that can ensure scientific robustness, particularly through disclosing conflicts of interest).

18. *See, e.g.*, Donald Kennedy, *Responding to Fraud*, 314 SCI. 1353, 1353 (2006) (describing how falsified science reports were retracted from publication and outlining various means that the magazine can use to combat false science in the future).

19. *See, e.g.*, Ed Yong, *How Reliable Are Psychology Studies*, THE ATLANTIC (Aug. 27, 2015), https://www.theatlantic.com/science/archive/2015/08/psychology-studies-reliability-reproducability-nosek/402466/; Munafo, Nosek, Dorothy, Bishop, Button, Chambers, Percie du Sert, Simonsohn, Wagenmakers, Ware & P.A. loannidis, *supra* note 17.

20. *See, e.g.*, Sheila Jasanoff, *Quality Control and Peer Review in Advisory Science*, *in* THE POLITICS OF SCIENTIFIC ADVICE: INSTITUTIONAL DESIGN FOR QUALITY ASSURANCE 19 (Justus Lentsch & Peter Weingart eds., 2011); Sheila Jasanoff, *Technologies of Humility: Citizen Participation on Governing Science*, 41 MINERVA 223 (2003); Heather Douglas, *Inserting the Public Into Science*, *in* DEMOCRATIZATION OF EXPERTISE?: EXPLORING NOVEL FORMS OF SCIENTIFIC ADVICE IN POLITICAL DECISION-MAKING 153 (2005).

tions that are instead driven by ideology and values.[21] If too much deference is given to the findings of scientists, society may be abdicating important policymaking based on an incomplete appreciation of the socially constructed features of empirical inquiry.[22] By contrast, though, if too little deference is given to science, then society may find itself missing out on important discoveries that have urgent implications for our collective health and well-being.

By harnessing the foundational features that tend to make science distinctive—namely, vigorous skepticism and rigorous peer review[23]—the Consensus Rule surmounts both of these familiar challenges arising in science-policy. With respect to the first challenge, the Consensus Rule seems to assume that, *if* there is a scientific consensus, the underlying evidence must be reliable since it has been internally vetted. And with respect to the second challenge, by drawing on the consensus in science, the Consensus Rule supposes that most of the idiosyncratic values held by individual scientists drop out and we are left with findings that are more thoroughly grounded in empirical methods because of the rigorous internal scrutiny. Scientific consensus thus provides a magic bullet, of sorts. The risk of hidden values corrupting research findings are reduced by internal scrutiny (challenge 2), while this same vetting provides a useful mechanism for catching and culling out manipulated science (challenge 1). In settings where there is no consensus, by contrast, the jury is tasked with filling in the many value-laden gaps that science leaves behind.[24]

II. DRAWING ON REGULATORY EXPERIENCE TO TROUBLESHOOT POTENTIAL CHALLENGES FOR THE CONSENSUS RULE

The Consensus Rule offers a number of benefits to the current state of evidence law. Not only will the Consensus Rule help overcome our precarious reliance on nonscientist judges to serve as gatekeepers in evaluating what constitutes "reliable" scientific testimony, but the Consensus Rule should provide thinly financed litigants with a vastly more accessible and affordable approach to fact-finding. Both plaintiffs in contingency-fee based tort cases and indigent criminal defendants should encounter fewer expenses—as compared to the multi-factorial and protracted *Daubert* hearings—in debates over whether there is or is not a scientific consensus on contested facts.

However, when the Consensus Rule intersects with more difficult cases, at least in the toxic tort arena, implementation may not be quite as

21. *See, e.g.*, Bennett Holman & T. Wilholt, *The New Demarcation Problem,* 91 STUD. HIST. & PHIL. SCI. 211 (2022).

22. *See* Daniel Sarewitz, *How Science Makes Environmental Controversies Worse,* 7 ENV'T SCI. & POL'Y 385 (2004).

23. *See, e.g.*, HELEN E. LONGINO, SCIENCE AS SOCIAL KNOWLEDGE: VALUES AND OBJECTIVITY IN SCIENTIFIC INQUIRY 80 (1990) (underscoring role of critical and diverse scrutiny in science); NAOMI ORESKES, WHY TRUST SCIENCE? (2020) (same).

24. Cheng, *supra* note 2, at 437.

smooth as Cheng envisions. I raise several concerns drawn from experience in environmental regulation, which tends to implicitly use a similar kind of consensus rule to inform rulemakings. More specifically, several public health and environmental agencies in the United States are required by Congress to set science-based standards for pollution or make science-intensive decisions on individual products with regard to their potential for unreasonable risk.[25] To fulfill this mandate, the agencies employ scientific staff and sometimes empanel external science panels to provide a soft kind of "consensus" about what the scientific literature suggests on key topics.[26] Their scientific work then feeds into a collaborative exchange with a team of scientists, economists, and other policymakers who identify target ranges of "safe" concentrations by filling in the many gaps in this scientific consensus with value choices.[27]

In these efforts, which have occurred over the last fifty years, implementing agencies have found themselves embroiled in often heated conflicts over their scientific analyses.[28] As just one example, agency science-intensive decisions have been sharply critiqued by the National Academies of Science (NAS) in book-length reports for at least thirty-five years.[29] A recurring source of criticism in the NAS reports spotlights the agencies' failure to adequately explain or defend specific value-based choices, such

25. *See, e.g.*, Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a) (1994); Federal Insecticide, Fungicide, and Rodenticide Act of 1972 § 3(c)(5)(D), 7 U.S.C. § 136a(c)(5)(D) (1994) (prohibiting pesticides that "cause unreasonable adverse effects on the environment"); Safe Drinking Water Act § 1412(b)(4), 42 U.S.C. § 300g-1(b)(4) (1988) (maximum drinking water contaminants are "set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety"); Clean Air Act § 109(b)(1), 42 U.S.C. § 7409(b)(1) (1988) (standards for commonplace "criteria" air pollutants must "allow[ ] an adequate margin of safety . . . requisite to protect the public health").

26. *See, e.g.*, SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990); Thomas O. McGarity, *The Internal Structure of EPA Rulemaking*, 54 LAW & CONTEMP. PROBLEMS 57, 60–61 (1994).

27. *See, e.g.*, ELIZABETH FISHER & SIDNEY SHAPIRO, ADMINISTRATIVE COMPETENCE (2020); McGarity, *supra* note 26.

28. *See, e.g.*, Holly Doremus, *Scientific and Political Integrity in Environmental Policy*, 86 TEX. L. REV. 1601 (2008) (identifying some of the dangers of providing staff too much authority); BRENNAN CTR. FOR JUST., PROPOSALS FOR REFORM VOLUME II: NATIONAL TASK FORCE ON RULE OF LAW & DEMOCRACY (2019), https://www.brennancenter.org/our-work/policy-solutions/proposals-reform-volume-ii-national-task-force-rule-law-democracy [https://perma.cc/H6GM-GN7T]; Jori Reilly-Diakun, *Addressing Blurred Lines: Institutional Design Solutions to Transgressions Across the Science-Policy Boundary*, 49 TEX. ENV'T L.J. 199, 218–20 (2019).

29. See, e.g., NAT'L RSCH. COUNCIL, REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE (2011) [hereinafter REVIEW OF EPA DRAFT ASSESSMENT OF FORMALDEHYDE]; NAT'L RSCH. COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994); NAT'L RSCH. COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) [hereinafter RISK ASSESSMENT IN FED. GOV. REPORT].

as how to weight the disparate evidence, factor in variability, and address uncertainties and gaps in the scientific record.[30]

The fallout from these agency struggles offers potential lessons for the Consensus Rule as well. I identify three distinct lessons drawn from regulatory experience.

A. *Separating Values from Science*

The Consensus Rule defers to scientists on what they think the science says on a question. However, by design that formulation of the Consensus Rule also requires us to trust the scientists' own consensual judgment about when and whether their own conventions and practices might be intruding on value questions that are best left to the jury (or regulators). The underlying choices—for example, how scientists chose to draw the line between science and values, or which values and subjective judgments they select in devising their methods and analyses—are effectively black-boxed from legal decisionmakers and thus are technically invisible, at least from my reading of the proposal. The Consensus Rule thus runs into potential trouble with respect to one of the systematic challenges familiar in science-policy; providing a suitable way to demarcate "science" from values to ensure that the scientists are not afforded too much discretion to decide policy.[31]

Most dramatically, some "consensuses" within scientific specialties might be developed to advance a particular end or policy purpose. Forensic science is a classic example.[32] Forensic science exists because prosecutors commission it,[33] and the number of troubling methodological blind spots in this type of evidence is now well-established.[34] Blanket deference to this community's views provides one of the most dramatic examples of the hazards of deferring too blithely to a "scientific" consensus.[35]

But even in less overtly policy-driven settings, there are still significant risks of the blurring of science and policy in the black-boxing approach adopted by the Consensus Rule. At least in environmental and public health regulation, we have learned over the last fifty years that blanket deference to scientists sometimes allows them to insert their own idiosyn-

30. *See, e.g.*, Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995) (summarizing these concerns and elaborating on them).

31. *See supra* notes 20–22 and accompanying text.

32. *See generally* NAT'L RSCH. COUNCIL, STRENGTHENING FORENSIC SCIENCE IN THE UNITED STATES: A PATH FORWARD (2009) [hereinafter STRENGTHENING FORENSIC SCIENCE IN THE UNITED STATES].

33. *See, e.g.*, Simon A. Cole, *Who Will Regulate American Forensic Science?*, 48 SETON HALL L. REV. 563, 567 (2018).

34. *See* STRENGTHENING FORENSIC SCIENCE IN THE UNITED STATES, *supra* note 32.

35. Cheng seems to acknowledge this problem. *See* Cheng, *supra* note 2, at 455–56.

cratic, albeit collective values into scientific advice.[36] This occurs because the scientists are being asked to extrapolate from a discrete set of research studies (e.g., the level of a toxicant that causes adverse effects in a mouse) to a much broader policy question (e.g., a "safe" dose of a toxin for the population for all potential adverse effects). The established scientific research provides only pinpointed empirical insights that arise within this broader regulatory project.

For example, determining a safe dose of a carcinogen in drinking water could raise dozens of "inference" junctures where values are needed to move the inquiry along.[37] The schematic at Figure 1 below oversimplifies some of these sub-questions that zig-zag between scientific and non-scientific questions. In the sub-questions below the line, there are scientifically plausible options, but selecting the best option is not based exclusively or often even primarily on existing scientific knowledge since the questions lie beyond current experimental methods.

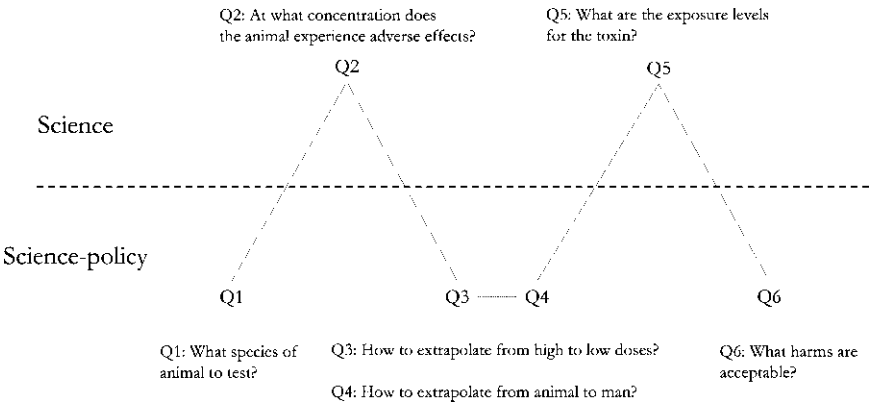

Figure 1

Causal questions arising in toxic tort cases (and likely in some other types of cases) necessarily entail this same type of zig-zag of values and science because of the rampant scientific uncertainties.[38] Indeed, one set of researchers remarked that the cumulative uncertainties (and requisite value choices) can be so significant that they lead to plausible outcomes that range from whether one has enough money to buy a cup of coffee or finance the national debt.[39]

36. *See, e.g.*, Wagner, *supra* note 30.

37. *Id.* at 1619–27 (laying out this framework).

38. *See, e.g.*, Carl Cranor, *A Framework for Assessing Scientific Arguments: Gaps, Relevance and Integrated Evidence*, 15 J.L. & POL'Y 7, 14–25 (2007) (outlining the major steps in non-deductive reasoning typically needed to weave together existing pinpoints of research to determine causation in toxic torts).

39. C. Richard Cothern, William A. Conigilo & William L. Marcus, *Estimating Risk to Human Health*, 20 ENV'T. SCI. & TECH. 111, 115 (1986).

And the simplified schematic in Figure 1 does not begin to do justice to the many values that occur even at the pinpoints above the line where some scientific information is available.[40] For example, there may be dozens or even thousands of toxicological studies that test the effects of a particular toxin on animals. Value judgments are thus required to synthesize this evidence. If animals react differently from one another, but we are not sure why or what that means for human exposure to the toxin, how do we collate the disparate results? And if the studies are of varied quality in terms of their underlying laboratory conditions, sample size, and methods, how do those concerns affect the weighting of their findings? Some studies will be industry-sponsored, should they be discounted? And on and on. Extrapolating these pinpoints of scientific insight from numerous, individual research studies clustered around the questions lying above the line to a broad question of causality thus necessarily entails the incorporation of many value judgments to make the leaps of faith to a larger causal question.[41]

As already noted, early in the science-intensive regulatory decisions (in the 1980s), the NAS in fact took the EPA to task for not making these extrapolatory choices—what they called "inference options"—explicit. Instead, the NAS accused the EPA of engaging in a type of science charade by black-boxing them as "scientific" judgments.[42] Ultimately, the EPA acceded and developed policy-based cancer guidelines and similar directives that explicitly identified the value choices that would fill the many gaps left in the scientific record.[43] For example, under these guidelines, risk assessors are directed to use specific protective values as default choices—for example, assuming that animals behave similar to man and extrapolating from high to low doses following a linear dose-response curve—despite other scientifically plausible options.[44] In terms of how the agency synthesizes disparate evidence to reach a "consensus" for the pinpointed questions above the line, the EPA continues to struggle to develop systematic methods for how to weight diverse studies that bear on a particular, narrow sub-question. And the NAS continues to press the EPA for greater clarity on these issues to ensure that the embedded value choices, even at

40. *See generally* Cranor, *supra* note 38.

41. *See id.*; *see also* Wagner, *supra* note 30, at 1619–27.

42. *See, e.g.*, RISK ASSESSMENT IN FED. GOV. REPORT, *supra* note 29.

43. *See* U.S. ENV'T PROT. AGENCY, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (2005), https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf [https://perma.cc/9M32-CC42] (this is the last iteration of the guidelines, which were initiated decades earlier).

44. Typically in these guidelines, the EPA reserves the possibility of rebutting the "default" values if the scientific evidence in a particular case justified a different extrapolatory assumption. But even in this case, the EPA specified how values would remain instructive in choosing among scientifically plausible options. *See id.* at App. A.

this "scientific" stage above-the-line, are clear to other scientists and policymakers.[45]

Returning to the use of a Consensus Rule in the court system, then, how will the Consensus Rule intersect with these challenges arising in difficult toxic tort cases? Will only the pinpoints of evidence (e.g., research on a particular type of mouse exposure to the toxicant) be the kind of "fact" for which we might draw out a consensus? And if scientists appear to arrive at a pinpoint consensus of "5 ppm" for the concentration at which a particular species of mouse experiences an adverse effect, what about extrapolating that "fact" to the plaintiff's case? Animals are dosed with very high levels since low doses would entail testing millions of subjects. How to extrapolate from these high doses to low? And from animal to man? The extrapolations necessarily require some value judgments. Certainly these challenges do not afflict all toxic cases equally. For those substances that rest on well-established and extensive human evidence and decades of consensus-work within the scientific community—for example the adverse health effects of tobacco, asbestos, DES, and a few others—the challenges identified here of rampant value-based choices are substantially less problematic. But for most of the difficult, contested causation cases, I worry that we will see some of these same difficulties familiar to regulation reappear in the courts' use of the Consensus Rule. Without a robust body of well-established human evidence, experts must necessarily weave together disparate, individual non-human studies using values. There is no way around this fact.

To be fair, this science-values challenge embedded in causal inquiries is also difficult for judges applying *Daubert*. Are the inferences used by experts testifying on causation testable? No. So some judges simply strike all expert testimony that incorporates inductive extrapolations and dismiss a plaintiff's case.[46] Yet these rulings ignore the fact that it is often not the plaintiff's fault there is no human evidence; the questions lie beyond the capabilities of existing research, yet the existence of an underlying causal connection remains scientifically plausible.[47] Indeed, in some litigation settings defendants deliberately exacerbate scientific uncertainties by *not* testing the safety of their own products (as was the case with Dupont and PFAS) or by commissioning ends-oriented research that distracts from the truth (as was the case with tobacco products).[48] When defendants them-

45. *See, e.g.*, REVIEW OF EPA DRAFT ASSESSMENT OF FORMALDEHYDE, *supra* note 29, ch. 9.

46. *See, e.g.*, Joseph Cecil, *Ten Years of Judicial Gatekeeping Under* Daubert, 95 AM. J. PUB. HEALTH S74 (2005) (discussing the Parlodel cases); Berger, *supra* note 3 (same); *see also* Cranor, *supra* note 38 (discussing this problem in some courts' resolution of toxic tort causation).

47. *See, e.g.*, Cranor, *supra* note 38.

48. *See, e.g.*, MICHAELS, *supra* note 15 (documenting the tobacco industries' longstanding strategy of commissioning ends-oriented research designed to throw doubt on mainstream research regarding the carcinogenicity of tobacco); Roy Shapira & Luigi Zingales, *Is Pollution Value Maximizing? The DuPont Case* 28 (Nat'l Bu-

selves bear significant responsibility for the rampant scientific uncertainties, it would seem more important to adopt plaintiff-friendly, protective-assumptions into risk assessments. Jurors should be allowed to consider the full body of available evidence, including assigning blame to defendants for exacerbating scientific uncertainties.[49]

In these difficult cases where the need for a *Daubert*-alternative is most urgent, then, it is hard to understand how the current formulation of the Consensus Rule will move the ball forward. It is possible that a litigant will argue there is a consensus on a contested causal question and simply allow experts to select their preferred values for all of the embedded inference options, thus black-boxing dozens or even hundreds of value choices. But this approach runs head long into the well-accepted hazards of science-policy by delegating too much policymaking authority to scientists.[50]

It seems more likely that one of two suboptimal outcomes will occur instead. One possibility is that litigants will focus on drawing out a consensus for individual sub-questions above the line. But this will then provide the jury with multiple specific consensus points that still need to be synthesized, thus running the risk of aggravating juror confusion and the "expert paradox." Or, alternatively, the litigants and judge will ultimately decide that there is no consensus on the causation question, opening the door up to litigants who then inundate jurors with whatever expert testimony they find helpful to prove a case. However, as discussed in Section II.C, for this pathway there will be no limit to the kinds of evidence litigants can introduce. As a result, the cases will rest primarily on the competence of counsel, with no meaningful oversight role reserved for the judge.

B. *Locating a Consensus*

Experience in the regulatory world raises another red flag regarding implementation of the Consensus Rule—it is not always easy to determine when or whether there is a consensus among scientists.[51] Thus, while a nonscientist might imagine that within science there are volumes of scientific treatises and review papers that set out a tentative "settlement" of the scientists' views on key issues, that is rarely the case. Or, at least in the regulatory world, these types of scientific consensus statement are few and far between. That is why Congress and the Executive Branch regularly finance the NAS to review high-profile scientific-intensive disputes. The

reau of Econ. Rsch., Working Paper No. 23866, 2017), https://www.nber.org/papers/w23866.pdf [https://perma.cc/2QG9-654F] (discussing DuPont's strategic ignorance on the toxicity of PFAS).

49. *See also* Cranor, *supra* note 38, at 56–57 (reaching a similar conclusion).

50. *See supra* notes 20–22 and accompanying text.

51. Harry Collins, *The Owls: Some Difficulties in Judging Scientific Consensus*, 67 VILL. L. REV. 877 (2022); Robert Evans, *The Consensus Rule: Judges, Jurors, and Admissability Hearings*, 67 VILL. L. REV. 883 (2022); Martin Wienel, *The Adversity of Adversarialism: How the Consensus Rule Reproduces the Expert Paradox*, 67 VILL. L. REV. 893 (2022).

NAS panels endeavor to locate a kind of consensus that has not yet been documented in the scientific literature.[52] Indeed, on reflection the dearth of published scientific consensus statements is not surprising. Recall that science embraces as one its core values vigorous skepticism, with a continuous churning of "paradigms" that seek to overthrow settled wisdom.[53] In this world, scientists are neither rewarded for, nor socialized to seek out points of agreement, but instead tend to view consensus with some suspicion.

Hence, it is not easy (at least on causation issues) to locate existing, written consensus statements that embody the full range of diverse, reputable scientists' views on a topic. But even if the statements did exist, there will be issues of timeliness given the dynamic nature of scientific discovery. A consensus fifteen years ago may be outdated and replaced with new findings or methodological approaches. At least that is what can happen in regulatory efforts to locate points of scientific agreement.[54]

In those (many) settings where there isn't an off-the-shelf statement of the communal scientific view on key issues that arise in regulation, then, the Consensus Rule will presumably encourage the use of panels or similar types of ex post efforts to gauge the scientific community's collective views on key questions arising in litigation. These panels might be devised somewhat like Judge Hall's or Judge Pointer's effort to empanel experts in the silicone breast implant litigation.[55] In the regulatory arena, the use of scientific panels is common.[56] Agencies often commission and fund panels of scientists to provide precisely this kind of guidance and input (after ensuring the scientists have sufficient direction on the major inference options and default values as just discussed).

However, while these scientific panels provide invaluable assistance to the regulatory process, they are not equivalent to the kind of consensus that might emerge organically from the scientific community. This is because there are a number of difficult (value) choices involved in establishing which scientists serve on the panels, the "charge" or questions they are tasked with answering, and the rules governing how they operate.[57] Just

52. *See, e.g.*, Ian Fein, *Reassessing the Role of the National Research Council: Peer Review, Political Tool, or Science Court*, 99 CAL. L. REV. 465 (2011); *see also* JASANOFF, *supra* note 26.

53. *See supra* note 23 and accompany text; *see also* THOMAS KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1962).

54. *See, e.g.*, James W. Conrad, Jr., *The Reverse Science Charade*, 33 ENV'T L. REP. NEWS & ANALYSIS 10306 (2003).

55. *See, e.g.*, Laural L. Hooper, Joe S. Cecil & Thomas E. Willging, *Assessing Causation in Breast Implant Litigation: The Role of Science Panels*, 64 L. & CONTEMP. PROBS. 139, 140–41 (2001).

56. *See, e.g.*, Joe Conley, *Conflict of Interest and the EPA's Science Advisory Board*, 86 TEX. L. REV. 165 (2007); Brian D. Feinstein & Daniel J. Hemel, *Outside Advisers Inside Agencies*, 108 GEO. L.J. 1139 (2020).

57. *See, e.g.*, BIPARTISAN POL'Y CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 19–23 (2009), http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf [https://perma.cc/

like the previous concern about black-boxing scientists' collective views on mixed science-policy questions, there are lively debates about what it means to develop a legitimate panel (on most contested scientific issues) within the scientific community. Although there can be disputes about virtually every feature of these panels, most controversies revolve around the foundational questions of how to re-create a representative mix of the respected disciplines and views on a given issue.[58] Can scientists with conflicts of interest serve, since they sometimes best know the state of the science on specific, applied topics? Which fields of expertise count—for example, just vascular neurologists, geriatric neurologists, or all neurologists? If there are camps or warring views within the scientific community, are multiple panels formed or must the consensus be drawn by focusing only those issues upon which the warring camps agree? How are dissenters factored into a consensus statement?

Since there still is no principled or accepted way to design these advisory boards to be comprised of an "ideal" mix of diverse, open-minded skeptics, there is little guidance for judging the legitimacy of a science advisory board after the fact.[59] One can thus imagine that when the stakes are high and these panels are producing "answers" that will be impactful to litigants and likely future litigants, there will be a great deal of controversy over these many design questions. Or at least that is the experience in the regulatory sphere. Indeed, because of the high stakes associated with scientific consensus panels, in regulatory decision-making it is the political officials who are tasked with responsibility for deciding whether and when to empanel expert bodies. Political officials also select which scientists will serve. Perhaps not surprisingly, as a result, a "stacking" problem sometimes arises in the composition of regulatory science advisory panels;[60] political officials can select scientists or even empanel advisory boards in blatantly ends-oriented ways.[61] One empirical study even found a consistent, positive correlation between the ideological composition of

S596-W3KH]; BRENNAN CTR. FOR JUST., *supra* note 28; Thomas McGarity & Wendy Wagner, *Deregulation Using Stealth Science Strategies*, 68 DUKE L.J. 1719, 1757–67 (2019).

58. *See, e.g.*, BIPARTISAN POL'Y CTR., *supra* note 57.

59. *See id.* The NAS guidelines are touted by the bipartisan panel as models for assembling the boards, but the success of the NAS is attributable also to their intense, survival-based incentives to implement science advisory boards successfully since their existence depends on this accomplishment. Without this "life-and-death" incentive, there will be wiggle room for some potentially serious lapses in ensuring a representative committee no matter how prescriptive the rules, particularly when the stakes are high.

60. *See, e.g.*, Robert Steinbrook, *Science, Politics, and Federal Advisory Committees*, 350 NEW ENG. J. MED. 1454, 1456 (2004).

61. *See id.*; McGarity and Wagner, *supra* note 57, at 1757–67. As just one of many examples, the EPA Administrator banned any scientists serving on advisory panels if they had received grants from the EPA within the prior three years (almost exclusively academics), while placing no restrictions on empanelling industry experts. *See* E. SCOTT PRUITT, ADMINISTRATOR, U.S. EPA, STRENGTHENING AND IMPROVING MEMBERSHIP ON EPA FEDERAL ADVISORY COMMITTEES (2017), https://

science advisory panels and the political party of the President at the time.[62]

Translating these risks to the Consensus Rule, one can imagine that locating a "consensus" from within science to guide litigation will be vulnerable to manipulation by clever advocates. Indeed, industry has been manufacturing biased consensus statements on high stakes issues for decades,[63] and these efforts would likely become even more prevalent in a post-Consensus-Rule world.

However, even if the artificially created panels can be assembled in ways that overcome these various obstacles, panel findings will not necessarily be free from controversy. Even blue-ribbon NAS panel reports can encounter a barrage of criticism from mainstream scientists who, recall, are culturally and professional programmed to be skeptical.[64] These criticisms are often not directed at "who" the scientists are or whether their "charge" was appropriate, but rather allege that the resulting scientific conclusions are not in fact representative because they reveal specific errors, dated understandings, or adopt value-laden assumptions.[65]

C. *Flood of Unreliable Science*

Combining these two warning lessons from our fraught experiences in regulatory science takes us to a final worry; if a consensus cannot be found to resolve scientific disputes, the Consensus Rule leaves no guardrails for the trial process. As I read Cheng's Consensus Rule, when there is no consensus over contested scientific facts, the jury decides the disputed science. The judge does not cull out unreliable science or play any oversight role at all. The resolution of these residual disputes over scientific controversies instead rests entirely with the jury.

But when a consensus cannot be found, the jury will almost inevitably face a flood of scientific evidence, some of which will likely not be reliable by scientific standards. Judges have long expressed concerns about the quality of the research entering courts. Judge Kozinski labeled some of it as "litigation science"—namely, research produced after a lawsuit commences to advance an advocate's position in litigation.[66] But even research produced well in advance of litigation can be similarly untrustworthy.[67] Regulated parties in particular have invested a great deal

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www.epa.gov/sites/production/files/2017-10/documents/final_draft_fac_directive-10.31.2017.pdf [https://perma.cc/G4TB-NLQZ].

62. *See* Hemel & Feinstein, *supra* note 56.

63. *See, e.g.*, MCGARITY & WAGNER, *supra* note 15, at ch. 8.

64. *See, e.g.*, Fein, *supra* note 52 (discussing these controversies).

65. *See id.*

66. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1318 (9th Cir. 1995).

67. *See supra* notes 15–17 and accompanying text; *see also* Mark R. Patterson, *Conflicts of Interest in Scientific Expert Testimony*, 40 WM. & MARY L. REV. 1313 (1999).

of resources in producing biased research decades before litigation is filed.[68]

To think that none of this unreliable research will be formally screened or even discouraged from entering a trial may lead to still more scientific errors arising in judicial fact-finding. Juries will be left to sort out the "fausse" and "junky"[69] from testimony that is trustworthy, with only the help of counsel's cross-examination. The number of experts testifying—and the range of issues on which they might opine—will likely increase substantially since there is no longer even a speed bump to admitting expert testimony.

Equally worrisome, in this free-for-all evidentiary space, lawyers may actually find that taking the low road—and not even endeavoring to show consensus—is far easier and more profitable. Plaintiff attorneys in particular can locate charismatic professional experts who are ready and willing to spout off confident (but unreliable) conclusions about cause and effect or any other contested scientific matter arising in court.[70] In these cases, defendants will find it nearly impossible to avoid trial, thus facing a raft of cases that may be brought on slim factual grounds simply to extract nuisance settlements.

One can also imagine corporate defendants increasing their already extensive investment in controlling the "information environment" by developing still more ends-oriented research to support their positions.[71] As discussed, there is considerable evidence that some corporations have managed to effectively control the state of scientific information bearing on the safety of their products, pollutants, and drugs by commissioning research, critiques, panels, and utilizing a range of other science-bending techniques.[72] In a litigation setting that accepts all of this ends-oriented scientific testimony with no judicial oversight whatsoever (although it remains unclear whether *Daubert* filters much of this "junk" out either),[73] corporate investment in bending science will prove even more lucrative.

Judicial efficiency will likely suffer as well. Without ways to preliminarily dismiss cases based on unreliable evidence, plaintiffs will file more cases and the courts will be without tools to cull out those cases that are based on unreliable expert evidence. We can imagine, too, that trials and even the discovery will be longer if most of the formal constraints on the admissibility of expert testimony are lifted. Without any guardrails, we can expect not only additional substantive, but added procedural complications for scientific fact-finding in courts.

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68. *See* Patterson, *supra* note 67.

69. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 158 (1999) (Scalia, J., concurring).

70. *See, e.g.*, PETER HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991) (providing a potentially exaggerated discussion of this risk).

71. *See, e.g.*, Shapira & Zingales, *supra* note 48.

72. *See supra* notes 15–17 and accompanying text.

73. *See, e.g.*, Patterson, *supra* note 67.

In this scenario where there is no governing consensus, then, the Consensus Rule would seem to yield an evidentiary approach that is not markedly better than the *Daubert* status quo. For all of its imperfections and complications, *Daubert* at least imposes some self-discipline on the types of experts that parties can introduce and on the nature of their testimony. Without this judicial oversight, counsel will have fewer incentives to be concerned with ensuring their expert testimony is rigorous. The absence of judicial oversight will likely produce negative spillovers within the scientific community as well. More ends-oriented experts—now finding a market for their wares—will endeavor to insert their views into the scientific literature, scientific meetings, and related events with even more frequency. In cases lacking a consensus, then, the Consensus Rule seems to abdicate far too much discretion to attorneys and jurors to make sense of unfiltered scientific evidence.

CONCLUSION: WHAT TO DO

Cheng is vastly more well-versed in both evidence law and the ins-and-outs of the Consensus Rule to decide whether any of these regulatory lessons are worth heeding and, if so, what to do about them. Perhaps most of these lessons from regulatory experience turn out to be minor, particularly with respect to the Consensus Rule's ability to improve on the status quo of *Daubert*.

Thus in closing, I want to reiterate that despite some misgivings about several implementation challenges arising under the Consensus Rule, Cheng's central recommendation that judges look to the scientific community for guidance on identifying reliable evidence is essential to the search for a better approach to evidence law. The fundamental problem with *Daubert,* as Cheng convincingly shows, is that the judges must work with criteria and evaluative metrics that do not line up with those the scientists themselves use in assessing the rigor of research.[74] Scientists are not concerned with "error rates," "general acceptance," or "falsifiability." Rather they scrutinize research by considering the methods, how the data was collected and analyzed, and seek assurances regarding the scientists' own disinterestedness and independence through conflict and authorship disclosures.[75] Scientists will also seek some assurance that researchers have been transparent about their research and followed the norms and conventions of science in providing reproducible work.[76] In some cases, the dataset underlying a study may even be reanalyzed to ensure that statistical data-dredging and other techniques were not used to produce the findings.[77]

74. *See* Cheng, *supra* note 2, at 414–19.

75. *See, e.g.*, Munafo, *supra* note 17; *see also* Oreskes, *supra* note 23.

76. *See, e.g.*, Munafo, *supra* note 17.

77. JAMA, for example, requires a data sharing statement that explains why data will not be shared for clinical trials. *See* JAMA Data Sharing Statement, https:/

Cheng's Consensus Rule is designed to effectively recreate that internal scientific vetting process, albeit black-boxing the conventions themselves, by focusing on the "output" or areas of scientific consensus. Yet if I am properly understanding the logic of the Consensus Rule, perhaps drawing out the individual conventions themselves as substantive guideposts for reliable expert testimony could provide an alternative approach.[78] Rather than locating areas of consensus on the substantive output of research, the procedural conventions of skepticism, disinterestedness, and authorship—to name several of the most important—would constitute the guideposts a judge would use to determine whether to exclude scientific testimony. This alternative approach is thus similar to Cheng's Consensus Rule with respect to drawing on scientific consensus for guidance, but it looks to long-standing procedural conventions regarding how to do science, rather than on substantive agreement among scientists regarding settled "facts."

Whatever the case, I'm immensely grateful for the opportunity to be included in this Symposium. The issues are pressing and important and Cheng's Consensus Rule is a project that has the potential to make a profound difference to how scientific evidence is understood and practiced.

/jamanetwork.com/journals/jama/pages/instructions-for-authors#SecDataSharingStatement [https://perma.cc/3826-S3WS] (last visited Nov. 8, 2022).

78. I try to flesh out this idea in a forthcoming piece prepared for a conference at Tilburg University, Tilburg, Netherlands (draft available from author upon request).