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It's Just a Shot Away: MMR Vaccines and Autism and the End of the Daubertista Revolution

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IT'S JUST A SHOT AWAY: MMR VACCINES AND AUTISM AND THE END OF THE *DAUBERTISTA* REVOLUTION

Professor Joëlle Anne Moreno[†]

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I. INTRODUCTION: THE VACCINE-AUTISM LINK AS A MODEL SCIENTIFIC CLAIM

A. *New Decisions from the Federal Vaccine Court*

Three years ago I wrote an article describing the increasingly prevalent claim that childhood measles, mumps, rubella (“MMR”) vaccines cause autism.¹ This article expressed concern that vaccine safety fears discouraged vaccination compliance and raised significant national and global public health concerns.² The article revealed that no legitimate scientific evidence supports the claim that MMR vaccines cause autism.³ Thus, healthcare decisions that should be based on facts are instead based on faith and fear. The article predicted that trends in social behavior would not shift until “judges [who] are the most powerful decision makers in the best position to shape the future both inside and outside the courtroom” began to resolve competing scientific claims.⁴ Finally, the article urged “judges who must decide the 5,000 pending civil cases against vaccine manufacturers [to] take a hard look at the quality of the scientific evidence.”⁵

1. Joëlle Anne Moreno, *Toxic Torts, Autism, and Bad Science: Why the Courts May Be Our Best Defense Against Scientific Relativism*, 40 NEW ENG. L. REV. 409 (2006).

2. *Id.*

3. *Id.* at 412–14.

4. *Id.* at 416.

5. *Id.*

By January 2009, 5,535 cases alleging that vaccines cause autism had been filed against the Department of Health and Human Services. On February 12, 2009, the first three autism “test cases”⁶ were decided by the United States Court of Federal Claims Office of Special Masters under the National Vaccine Injury Compensation Program (the “Federal Vaccine Court”).⁷

Childhood vaccines do *not* cause autism. This is the only reasonable reading of the decisions issued in *Cedillo v. Secretary of Health and Human Services*,⁸ *Hazlehurst v. Secretary of Department of Health and Human Services*,⁹ and *Snyder ex rel. Snyder v. Secretary of Department of Health and Human Services*.¹⁰

- In *Cedillo*, Special Master George L. Hastings concluded that because “[t]he overall weight of the evidence is *overwhelmingly contrary* to the petitioners’ causation theories,” petitioners “have failed to persuade me that there is validity to any of their *general causation* arguments, and have also failed to persuade me that there is any substantial likelihood that Michelle’s MMR vaccination contributed in any way to the causation of any of *Michelle’s own disorders*.”¹¹
- In *Hazlehurst*, Special Master Patricia E. Campbell-Smith based her decision on the fact that petitioners “failed to prove that their theory of vaccine-related causation is biologically plausible” and could not demonstrate “that the unsupported

6. OFFICE OF SPECIAL MASTERS, U.S. COURT OF FED. CLAIMS, THE AUTISM PROCEEDINGS, http://www.usfc.uscourts.gov/sites/default/files/vaccine_files/Background_on_the_autism_proceedings.pdf. These three cases were selected to serve as the first autism “test cases” by the Office of Special Masters. They were intended to test the following three theories of general causation: “(1) the theory that MMR vaccines and thimerosal-containing vaccines can combine to cause autism; (2) the theory that thimerosal-containing vaccines can cause autism; and, (3) the theory that MMR vaccines, without regard to any thimerosal additive, can cause autism.” *Id.* It should be noted that the third theory was later dropped because the evidence pertaining to that theory was duplicative of evidence presented on the first theory. *Id.*

7. 42 U.S.C. §§ 300aa-1 to -10 (2000); *see also* OFFICE OF SPECIAL MASTERS, U.S. COURT OF FED. CLAIMS, VACCINE PROGRAM BACKGROUND, http://www.usfc.uscourts.gov/sites/default/files/vaccine_files/VICP_General_Background.pdf.

8. No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009).

9. No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009).

10. No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009).

11. *Cedillo*, 2009 WL 331968, at *134.

links of their proposed causal chain cohere to establish a logical sequence of cause and effect”¹² Thus, “[h]aving carefully and fully considered the evidence, the undersigned concludes that the combination of the thimerosal-containing vaccines and the MMR vaccine are not causal factors in the development of autism and therefore, could not have contributed to the development of Yates’ autism.”¹³

- In *Snyder*, Special Master Denise K. Vowell held that “[t]o conclude that Colten’s condition was the result of his MMR vaccine, an objective observer would have to emulate Lewis Carroll’s White Queen and be able to believe six impossible (or, at least, highly improbable) things before breakfast.”¹⁴ Accordingly, “I must decide Colten’s case based on the evidence before me [and] [t]hat evidence does not establish an adequate factual basis from which to conclude that Colten’s condition was caused by his vaccines.”¹⁵

These findings are the result of a special two-step procedure designed by the Office of Special Masters (“OSM”) to facilitate resolution of the extensive number of pending autism claims. Under the OSM-mandated procedure, the Federal Vaccine Court first “conduct[ed] an inquiry into the *general causation issue* involved in these cases—*i.e.*, whether the vaccinations in question can cause autism and/or similar disorders, and if so in what circumstances—and then, second, appl[ied] the evidence obtained in that general inquiry to the individual cases.”¹⁶

To address questions of general and specific/individual causation, each special master reviewed an immense amount of scientific evidence. For example, Special Master George L. Hastings considered 23 separate medical expert reports, heard live testimony from 16 expert witnesses, and reviewed 658 medical

12. *Hazlehurst*, 2009 WL 332306, at *171.

13. *Id.* at *172. Thimerosal is a compound made from ethyl mercury and other components. Thimerosal was once used as a preservative in more than thirty vaccines licensed in the United States. *Cedillo*, 2009 WL 331968, at *17. Due to public safety concerns, thimerosal has not been used by vaccine manufacturers since 2001. See Gardiner Harris & Anahad O’Connor, *On Autism’s Cause, It’s Parents vs. Research*, N.Y. TIMES, June 25, 2005, at A1.

14. *Snyder ex rel. Snyder v. Sec’y of Dep’t of Health & Human Servs.*, No. 01-162V, 2009 WL 332044, at *198 (Fed. Cl. Feb. 12, 2009).

15. *Id.*

16. *Cedillo*, 2009 WL 331968, at *8.

journal articles.¹⁷ As the above-quoted excerpts reveal, all of the special masters agreed on the following two conclusions (as articulated by Special Master Hastings). First, the specific/individual causation claims were rejected because the medical evidence proffered by “the petitioners . . . failed to demonstrate that her[/his] vaccinations played *any role at all* in causing those [autism-related] problems.”¹⁸ Second, the general causation claims were rejected because “petitioners . . . *failed* to demonstrate that thimerosal-containing vaccines . . . or that the MMR vaccine *can* contribute to causing . . . autism”¹⁹

B. Can High-Profile Science-Based Cases Change Legal Decision Making from the Bottom-Up or the Top-Down?

The new Federal Vaccine Court cases raise questions about the interplay among law, science, and society. These questions could be explored from a variety of perspectives. This article starts from the premise that “scientific validity” is a term of art that connotes a “connection between a theory or results of a particular study and the empirical world.”²⁰ It shares the fundamental assumptions of

17. *Id.* at *13.

18. *Id.* at *1 (emphasis added).

19. *Id.* (emphasis added). These conclusions are not undermined by the fact that in March 2008 the Federal Vaccine Court awarded damages to the family of Hannah Poling. Poling *ex rel.* Poling v. Sec’y of Health & Humans Servs., No. 02-1466 V, 2008 WL 1883059, at *1 (Fed. Cl. Apr. 10, 2008). See Paul A. Offit, *Inoculated Against Facts*, N.Y. TIMES, Mar. 31, 2008, at OP. In *Poling*, medical expert testimony established that Hannah had a mitochondrial disorder that prevented her cells from processing nutrients and contributed to her autism. See *id.* Thus, the *Poling* case is distinguishable on its facts. It is further distinguishable on its law. In that case, without holding a hearing on the scientific evidence, the Federal Vaccine Court concluded that it was *medically plausible* that Hannah’s vaccines exacerbated her preexisting chronic neurological illness. See *id.* In the three February 2009 decisions, the Federal Vaccine Court explicitly clarified that “[t]he burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. . . . [and] [t]he showing of ‘causation-in-fact’ must satisfy the ‘preponderance of the evidence’ standard, the same standard ordinarily used in tort litigation.” *Cedillo*, 2009 WL 331968, at *2 (emphasis added). Following the *Poling* decision, Dr. Julie L. Gerberding, Director of the Centers for Disease Control and Prevention, issued the following statement: “Let me be very clear that the government has made absolutely no statement indicating that vaccines are a cause of autism. That is a complete mischaracterization of the findings of the case and a complete mischaracterization of any of the science that we have at our disposal today.” Gardiner Harris, *Deal in an Autism Case Fuels Debate on Vaccine*, N.Y. TIMES, Mar. 8, 2008, at A17.

20. KENNETH R. FOSTER & PETER W. HUBER, *JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS* 146 (1999).

contemporary legal philosopher Susan Haack that “scientific claims and theories are about natural phenomena and events, and so . . . whether those claims and theories are true or are false is still independent of whether you, or I, or anyone, *thinks* they are.”²¹ Thus, accurate decisions about science must be based on validity assessments that measure how well a scientific theory describes and explains the natural world.

This article explores the potential impact of high-profile science-based legal decisions on the tenets of social decisions about science using the new Federal Vaccine Court cases as a model. Scientific validity is not socially constructed (to paraphrase Susan Haack—science is true or false regardless of *whether we think it is*).²² But decisions about science are social behavior, and cases like the Federal Vaccine Court decisions involve scientific questions of global concern. Thus, these new cases provide a unique opportunity to explore and predict shifts in attitudes and behavior from two different perspectives: the bottom-up and the top-down.

First, all parents in all countries make healthcare decisions about their children. These decisions include vaccine compliance. Vaccine data is also routinely recorded and maintained. Thus, this article begins by exploring whether the Federal Vaccine Court cases can and will change the tenets of subsequent science-based decisions at a grassroots level.²³ Immediately after the Federal Vaccine Court decisions were released, the *New York Times* reported that the cases would deal a “blow to the movement arguing that vaccines lead to autism.”²⁴ Dr. Michael T. Bradley (a spokesman for the American Academy of Pediatrics) predicted that in response to the Federal Vaccine Court cases pediatricians will soon see less parental resistance to childhood vaccines.²⁵ The empirical data on vaccine compliance and disease outbreaks will eventually enable us to assess the accuracy of these predictions. If these predictions prove correct, they will signal a grassroots social shift away from the increasingly prevalent belief that vaccines are dangerous and, more specifically, that MMR vaccines cause

21. Susan Haack, Symposium, *Of Truth, in Science and in Law*, 73 BROOK. L. REV. 985, 995 (2008) (emphasis added) [hereinafter Haack, *Of Truth*].

22. *See id.*

23. *See infra* Part III.

24. Donald G. McNeil, Jr., *Court Finds No Link of Vaccine and Autism*, N.Y. TIMES, Feb. 13, 2009, at A16.

25. *Id.*

autism.²⁶ This shift will only occur if the Federal Vaccine Court decisions actually encourage parents to base future healthcare decisions on the facts embodied in the growing body of scientific evidence and discourage parents from continuing to make decisions based on fear and faith.²⁷

Second, all judges must decide cases that involve scientific information. Thus, this article will examine whether science-based legal decisions that do *not* involve typical “science and law” evidence questions can change the tenets of future decisions from the top-down. At this point, it is old news that the relationship between science and law is awkward at best because law and science have patently different standards, goals, and constraints. However, since the U.S. Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*²⁸ in 1993, the field of science and law within the legal academy has been dominated by evidence scholars and preoccupied with the “*Daubert* Revolution.”²⁹ Post-*Daubert* (“*Daubertista*”)³⁰ scholars have exercised virtual hegemony over the science and law field by generating a vast body of academic literature devoted to exploring judicial operation of the scientific evidence admissibility standards in a range of factual contexts. The

26. *Id.*

27. A recent opinion editorial in the *Los Angeles Times* had a different prediction noting that “[s]adly, a decision by the nation’s vaccine court won’t make much difference to the very vocal parents who refuse to let this theory [that MMR vaccines cause autism] die.” Editorial, *A Dose of Reality on Vaccines and Autism*, L.A. TIMES, Feb. 25, 2009, at A16.

28. 516 U.S. 869 (1995).

29. See, e.g., J. Davies, *Admissibility of Scientific Evidence in Courts*, 24 MED. & L. 243, 247–49 (2005) (*Daubert* led to a revolution in the admissibility of scientific evidence, evaluation of testimony, and expert opinions); David L. Faigman, Symposium, *The Law’s Scientific Revolution: Reflections and Ruminations on the Law’s Use of Experts in Year Seven of the Revolution*, 57 WASH. & LEE L. REV. 661, 661 (2000) (*Daubert* was “the shot . . . that ignited the revolution” signifying that “[t]he scientific revolution finally had reached the law”); Anthony Z. Roisman, *Parker v. Mobil Oil Corp.*, in ENVIRONMENTAL AND TOXIC TORT LITIGATION (ALI – ABA Course of Study Materials, Course No. SM072, 2007) (“Therein lies the revolution. In a nutshell, *Daubert* and its progeny . . . brought the scientific culture to the courtroom.”).

30. I refer to the proponents of the so-called “*Daubert* Revolution” as *Daubertistas* because, as William Safire recently noted, the suffix “[i]sta—the Spanish version of the English suffix *ist*, as its *ismo* is our *ism*—was adopted as a combining form in our language in 1928 with the *Sandinistas*, the name for the supporters of the Nicaraguan Socialist-Nationalist leader Augusto César Sandino.” William Safire, *Frugalista*, N.Y. TIMES, Nov. 21, 2008, at 16. I am also confident (based on a March 10, 2009 Google search that yielded just one unrelated hit) that this appellation is original.

new Federal Vaccine Court cases raise “science and law” concerns because the special masters evaluated complex and competing scientific claims and resolved science-based questions of global significance. However, these cases did *not* involve the application of evidentiary admissibility standards. For the past sixteen years, *Daubertista* scholars have generally ignored legal cases that arise in other disciplines even when courts engage in sophisticated and detailed analyses of vital and complex scientific questions, such as the exploration of evolution and Intelligent Design Theory in *Kitzmiller v. Dover Area School District*.³¹ If the Federal Vaccine Court cases fail to generate top-down effects by encouraging courts and legal commentators (who purport to inform and guide the law) to rely on derivative principles and methods as they confront new science-based legal controversies, there is something wrong with the entire field that must be challenged.

Finally, this article posits that the growing interdependence of science, law, and society requires increasingly sophisticated thinking about science.³² These decisions can be facilitated by a new, more inclusive transdisciplinary approach to science-based controversies, which might also help ameliorate or overcome common systemic social obstacles to good decisions. Thus, this article concludes with the caution that even the most promising (and apparently pro-science) changes in political parties or players will not provide a panacea.

II. THE MODEL SCIENTIFIC CLAIM: CHILDHOOD VACCINES CAN CAUSE AUTISM

A. *Fear: What Is Autism?*

Autism was first described in 1943.³³ Autism and autism spectrum disorder are terms that “describe a set of developmental disorders characterized by impairments in social interaction, impairments in verbal and non-verbal communication, and stereotypical restricted or repetitive patterns of behavior and interests.”³⁴ Autistic symptoms vary widely among individuals.³⁵

31. 400 F. Supp. 2d 707 (M.D. Pa. 2005).

32. See *infra* Part III.

33. See *Cedillo v. Sec’y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *7 (Fed. Cl. Feb. 12, 2009) (discussing Dr. Leo Kanner, *Autistic Disturbances of Affective Contact*, 2 NERVOUS CHILD 217 (1943)).

34. *Id.*

Parents tend to worry about autism for the first few years because the disorder is not normally diagnosed until children are toddlers.³⁶ In addition, as the below statement from Dr. Sanjay Gupta reveals, parents may also be unnerved by the fact that we do not know what causes autism.

As many as one in every 166 children in this country is found to have autism, and doctors still don't know why. Doctors point to genetics and environment as culprits, but it could be more complicated than that. The latest research shows these children are not necessarily born with autism but with the potential to develop it. What exactly are these outside factors? It's hard to pinpoint. What we eat, what we breathe, what we drink—all these things could play a role. Some doctors say the increase is due to a change in the way the condition is diagnosed[;] kids who were once labeled mentally retarded are now being labeled as autistic.³⁷

A final source of fear is that the rates of reported autism cases have increased over the past six decades.³⁸ For example, a very recent study published in the *Archives of General Psychiatry* found that from 1995 to 2007, autism rates in California rose every year.³⁹ However, this data should be balanced against the fact that many autism experts postulate that “the increase in diagnosis does *not* represent a real increase in the incidence of the condition, [but] result[s] instead from a broadening of the diagnostic criteria for autism, improved recognition of autism, and other factors.”⁴⁰ In light of autism's potential severity, unknown etiology, and

35. *Id.*

36. *Id.* at *80 (noting that a causal inference cannot be assumed simply because the first dose of MMR vaccine is normally administered to children between twelve and eighteen months and the first symptoms of autism normally present themselves during the second year of life).

37. *Autism Rates Up Despite Removal of Mercury from Vaccines*, CNN.COM, Dec. 22, 2008, <http://www.cnn.com/2008/HEALTH/dailydose/12/04/autism.mercury>. Dr. Gupta is CNN's Chief Medical Correspondent.

38. *Cedillo*, 2009 WL 331968, at *7.

39. Robert Schechter & Judith K. Grether, *Continuing Increases in Autism Reported to California's Developmental Services System: Mercury in Retrograde*, *ARCHIVE GEN. PSYCHIATRY*, Jan. 2008, at 19, 21–22, available at <http://archpsyc.ama-assn.org/cgi/reprint/65/1/19>. It is noteworthy that this study also concluded that thimerosal was not a primary cause of increased autism rates. *Id.* at 22–23. This conclusion was based on the fact that autism rates continued to rise after 2001, which was the year that vaccine manufacturers stopped using thimerosal to preserve childhood vaccines. *Id.* at 20.

40. *Cedillo*, 2009 WL 331968, at *7.

presumed increase in prevalence, parents' fears about autism are understandable.

B. Faith: Developing the Claim that MMR Vaccines Cause Autism

People first began to believe that childhood MMR vaccines cause autism after the 1998 publication of a study by British physician Dr. Andrew Wakefield in the medical journal *The Lancet*.⁴¹ This study involved twelve children who had developed symptoms of autism (along with a new inflammatory bowel disorder) after receiving MMR vaccines.⁴²

With flashbulbs popping, Wakefield stepped up to the bank of microphones: he and his colleagues, he said, had discovered a new syndrome that they believed was triggered by the MMR (measles, mumps, rubella) vaccine. In eight of the 12 children in their study, being published that day in the respected journal *The Lancet*, they had found severe intestinal inflammation, with the symptoms striking six days, on average, after the children received the MMR. But hospitals don't hold elaborate press conferences for studies of gut problems. The reason for all the hoopla was that nine of the children in the study also had autism, and the tragic disease had seized them between one and 14 days after their MMR jab. The vaccine, Wakefield suggested, had damaged the intestine—in particular, the measles part had caused serious inflammation—allowing harmful proteins to leak from the gut into the bloodstream and from there to the brain, where they damaged neurons in a way that triggered autism. Although in their paper the scientists noted that “we did not prove an association” between the MMR and autism, Wakefield was adamant. “It’s a moral issue for me,” he said, “and I can’t support the continued use of [the MMR] until this issue has been resolved.”⁴³

The following year, new speculation arose that thimerisol (a vaccine-preserving compound that contains ethylmercury) was either *the* cause or a contributing cause of MMR vaccine-related

41. Andrew J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637 (1998), available at <http://briandeer.com/mmr/lancet-paper.pdf>.

42. *Id.* at 637.

43. Sharon Begley, *Anatomy of a Scare*, NEWSWEEK, Feb. 21, 2009.

autism.⁴⁴

The bottom-up, grassroots social impact of Dr. Wakefield's study was significant.⁴⁵ This new scientific claim precipitated a significant shift in public attitudes and behavior. The Wakefield study derogated from the previously prevailing view that "immunization was . . . the greatest public health achievement in the United States in the twentieth century."⁴⁶ Since the release of the study in 1998, British MMR vaccination rates have dropped from 92% to 80%.⁴⁷ There is also new evidence that British vaccination rates are now so low that they threaten "herd immunization" effects.⁴⁸ Individual vaccines work by triggering an immune system response, but vaccinating populations also creates herd immunity even when some members of the community are not vaccinated.⁴⁹ Herd immunity occurs because vaccinating a significant portion of the population also protects the unvaccinated by reducing the chance that they will encounter an infected individual.⁵⁰ The new concerns about decreased herd immunity are not purely speculative. Over the past decade, the number of reported measles cases in Britain has increased almost thirty-fold from 56 to 1,348.⁵¹

The grassroots effects of the Wakefield study have crossed the pond and spread to decisions about other childhood vaccines. In 2006, 12% of American parents reported that they refused to vaccinate their children because vaccines are unsafe.⁵² Just two years later, this number had increased by a third so that by 2008, 16% of American parents were refusing some or all childhood vaccines.⁵³ The public health effects of lower vaccine compliance rates have been significant.

44. *Cedillo*, 2009 WL 331968, at *7.

45. See Brian Deer, *MMR Doctor Andrew Wakefield Fixed Data on Autism*, SUNDAY TIMES (LONDON), Feb. 8, 2009, available at http://www.timesonline.co.uk/tol/life_and_style/health/article5683671.ece.

46. Richard G. Judelsohn, *Vaccine Safety: Vaccines Are One of Public Health's Greatest Accomplishments*, SKEPTICAL INQUIRER, Nov./Dec. 2007, available at <http://www.csicop.org/si/2007-06/judelsohn.html>.

47. Arthur Allen, *In Your Eye, Jenny McCarthy*, SLATE, Feb. 12, 2009, <http://www.slate.com/id/2211156>.

48. *Id.*

49. T. Jacob John & Reuben Samuel, *Herd Immunity and Herd Effect: New Insights and Definitions*, 16 EUR. J. EPIDEMIOLOGY 601, 601 (2000).

50. *Id.*

51. Allen, *supra* note 47.

52. *Id.*

53. *Id.*

[S]adly, with more parents delaying or refusing immunizations, some of these diseases are rising in number again. Children are suffering and dying from influenza, pertussis and meningitis when vaccines could have protected many of them. Recently five cases of Hib (haemophilus) in Minnesota—in which one infant died—reflected the effect of parents more frequently delaying or refusing vaccinations. Hib had been quiet for more than a decade.⁵⁴

Data gathered following a very recent outbreak of chicken pox in Washington State revealed that approximately one-third of parents currently do not comply with state immunization regulations.⁵⁵

This is not the first time that vaccine safety concerns have created serious grassroots public health problems. Before the discovery of a pertussis vaccine, the disease was a leading worldwide cause of infant death.⁵⁶ By 1960, countries that had started to provide vaccine coverage experienced a dramatic decrease in the frequency and severity of pertussis cases.⁵⁷ That same year, Dr. Justus Ström published a study claiming that whole cell (active) pertussis vaccines caused neurological complications in one out of six thousand cases.⁵⁸ A 1967 investigation by the Swedish Royal Medical Board corrected Dr. Ström's reaction rate to one out of fifty thousand.⁵⁹ However, this new information did little to correct responsive shifts in social behavior from the bottom-up or the top-down. The public responded to the media frenzy that followed Dr. Ström's study by refusing pertussis vaccines and, predictably, pertussis infection rates started to climb.⁶⁰ Government

54. Todd Wolynn, *What Vaccine Dilemma?*, PITT. POST-GAZETTE, Mar. 8, 2009, at G1.

55. Press Release, Wash. State Dep't of Health, *Childhood Vaccine Rates Rising—Outbreaks Show Need for More Coverage* (Apr. 21, 2008), http://www.doh.wa.gov/Publicat/2008_news/08-059.htm. Whooping cough is one of the leading causes of vaccine-preventable deaths. Throughout the world there are approximately three hundred thousand deaths per year (most of these deaths are infants who are unvaccinated or have not received the complete set of vaccinations). See LOGAN BRENZEL ET AL., *DISEASE CONTROL PRIORITIES PROJECT, VACCINE-PREVENTABLE DISEASES* 398 (2006), <http://files.dcp2.org/pdf/expressbooks/vaccine.pdf>.

56. William John Hoyt, Jr., *Anti-Vaccination Fever: The Shot Hurt Around the World*, SKEPTICAL INQUIRER, Jan. 2004, available at <http://csicop.org/si/2004-01/anti-vaccination.html>.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

policymakers in Sweden, Japan, and Australia opted to abandon pertussis vaccines, and these countries experienced pertussis epidemics.⁶¹ An acellular (passive) formulation of the vaccine that has never been shown to cause neurological complications was introduced in the 1980s.⁶² However, acellular vaccine refusal rates and pertussis infections rates remain high in both Sweden and Australia.⁶³

Distorted numbers, confusion of correlation with causation, and statistical innumeracy certainly played roles in this sad [pertussis vaccine] story. Sensationalist media campaigns fanned the glowing embers. But in each of the countries that experienced the raging fires of epidemics there were other forces at work. Most prominent in passive anti-vaccination movements were religious groups whose opposition was based on religious or moral grounds. Prominent in both passive and active anti-vaccination movements are followers and practitioners of homeopathy, chiropractic, and natural and alternative medicine.⁶⁴

There are notable similarities between the bottom-up and top-down social responses to fears about pertussis vaccine safety and the more recent concerns about MMR vaccines and autism. Although pertussis infection rates in the United States have been very low since the 1980s, a recent pertussis outbreak in Washington State has been attributed to generalized fears about vaccine safety based on MMR vaccine-related concerns.⁶⁵

The current trend of vaccine shunning may be more problematic because it is facilitated by easy public access to information and misinformation. Any electronic search for general information about autism inevitably yields autism advocacy websites that advance the claim that MMR vaccines cause autism. One prominent proponent of the MMR vaccine-autism link is Dr. Mark Geier, whose work is featured on many popular autism information websites, such as autismmedia.org.⁶⁶ [Autismmedia.org](http://autismmedia.org), which is run

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

65. Washington State currently has an immunization compliance rate of approximately 70%. Press Release, Wash. State Dept. of Health, *supra* note 55.

66. FAIR Autism Media, The Vaccine-Autism Connection, <http://autismmedia.org/media2.html> (last visited Apr. 13, 2009).

by the Foundation for Autism Information & Research, describes Dr. Geier as a Johns Hopkins professor and N.I.H. specialist whose epidemiological studies have demonstrated a significant link between vaccines and autism.⁶⁷ The website provides links to Dr. Geier's video-streamed lectures and to his many articles on vaccine-caused autism.⁶⁸ Politicians, such as Senator Joseph Lieberman, Representatives Dan Burton and Dave Weldon, and former New York Governor George Pataki, have all advanced vaccine-safety concerns.⁶⁹ The autism-related dangers of MMR vaccines have also entered the field of popular entertainment. The FX series "The Shield" featured a multi-episode storyline that seemed to provide medical evidence establishing a connection between MMR vaccines and autism.⁷⁰ These claims are also regularly repeated in the popular media by celebrity spokespeople such as Jenny McCarthy and Jim Carrey.⁷¹

C. Fact: Does the Body of Scientific Evidence Support the Claim that MMR Vaccines Cause Autism?

The three recent Federal Vaccine Court decisions contain more than six hundred pages of text that is almost entirely devoted to the medical evidence that supports or refutes the claim that MMR vaccines cause autism. A detailed discussion of all of the scientific evidence considered by the three special masters is beyond the scope of this article. However, to illustrate how the Federal Vaccine Court addressed the scientific questions about vaccine safety data, it is useful to examine the court's assessment of

67. *Id.*

68. *Id.*

69. See Moreno, *supra* note 1, at 410. See also Judelsohn, *supra* note 46 (noting that "[d]espite scientific proof and a long track record of vaccine safety, we see public policy based on junk beliefs, misinformation, fear, and mass hysteria.").

70. Autism advocacy web sites have referred to this television show with approval. See, e.g., Autism Speaks, <http://www.cureautismnow.org/home/article/news/4320.jsp> (last visited Apr. 13, 2009).

71. See Allen, *supra* note 47. More recently, the actress Amanda Peet has become the celebrity spokesperson for the vaccine advocacy group "Every Child by Two." See Dan Childs, *X-Files Actress on Vaccines: Ignore the Stars*, ABC NEWS.COM, Aug. 15, 2008, <http://abcnews.go.com/Health/AutismNews/Story?id=5483159&page=1>. Peet has also created a website, vaccinateyourbaby.org, which counters web-based scientific misinformation by providing easy access to the legitimate medical research demonstrating the lack of any connection between MMR vaccines and autism. *Id.*

the petitioners' claim that the vaccine preservative thimerosal⁷² causes autism.

Petitioners' argument that exposure to thimerosal causes autism was principally supported by evidence provided by Dr. H. Vasken Aposhian, a professor of biology, pharmacology, and toxicology at the University of Arizona.⁷³ According to Dr. Aposhian, thimerosal-containing vaccines can damage children's immune systems.⁷⁴ Dr. Aposhian also opined that autism could be caused by a disorder that prevents children from effectively eliminating mercury.⁷⁵

The special masters balanced petitioners' medical expert evidence on the safety risks of thimerosal against evidence presented by respondents' expert, Dr. Jeffrey Brent, a medical toxicologist from the University of Colorado.⁷⁶ For example, Special Master Hastings began with a comparison of the experts' qualifications, noting that it was significant that Dr. Brent (but not Dr. Aposhian) had professional experience treating children for mercury toxicity.⁷⁷ According to the court, this experience informed his expert opinion that "the available evidence does *not* justify a conclusion that the thimerosal contained in childhood vaccines can damage infants' immune systems."⁷⁸ Special Master Hastings also discussed Dr. Brent's opinion that because "the many different types of mercury have toxicological properties quite different from one another . . . it is inappropriate to generalize . . . from one form of mercury to another."⁷⁹

72. *See supra* note 13 (defining thimerosal).

73. *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *17-19 (Fed. Cl. Feb. 12, 2009).

74. *See id.* at *18.

75. *See id.* at *17.

76. *See id.* at *17-19.

77. *See id.* at *17.

78. *Id.* at *18.

79. *Id.* The distinction between methyl and ethyl mercury is an important point that has been raised elsewhere on numerous occasions. For example, in *Toxic Torts, Autism, and Bad Science: Why the Courts May Be Our Best Defense Against Scientific Relativism*, I noted that:

The first inquiry must begin with the fact that mercury exists in different chemical structures. Concerns about the dangers of mercury exposure have focused on methyl mercury, which has been clearly linked to a variety of neurological disorders. Thimerosal contains ethyl mercury, which is a different chemical compound. Because methyl and ethyl mercury have different chemical structures, they do not present the same health risks.

Moreno, *supra* note 1, at 412 (further explaining that methyl mercury easily

The Federal Vaccine Court also considered evidence presented by Dr. Brent that explained the difference between *in vitro* studies (“in which a cell or other entity is removed from a living being and studied in a ‘petri dish’ or other laboratory setting”)⁸⁰ and *in vivo* studies (“done on living humans or other animals”).⁸¹ The court’s comparison of *in vitro* and *in vivo* studies included recognition of the general scientific principle that *in vitro* animal studies are useful mainly for generating scientific hypotheses,⁸² and that this principle would apply to a wide range of science-based legal decisions.⁸³ In the context of the instant case, Special Master Hastings relied on the distinction between *in vitro* and *in vivo* studies when he agreed with Dr. Brent’s conclusion that “what happens to a cell in a laboratory when exposed to a chemical might be completely different from the effect that such chemical might have on a similar cell if that cell was part of a living being.”⁸⁴ The court also recognized that this distinction highlighted inherent problems with petitioners’ scientific claims because their *in vitro* studies exposed (mouse) cells to high doses of thimerosal, while human cells would have instead been exposed to low doses of ethylmercury.⁸⁵ Thus, Special Master Hastings concluded that “a thorough examination of the record makes it clear that there is *no* evidence, beyond Dr. Aposhian’s own assertion, that *ethylmercury, in the very small amounts contained in thimerosal-containing vaccines, can damage infant immune systems, or otherwise contribute to autism in any way.*”⁸⁶

This brief discussion of the Federal Vaccine Court’s exploration of the scientific claims that support or refute a causal link between thimerosal and autism is just the tip of the iceberg. In each of the three cases, the special masters carefully considered a vast quantity of complex scientific information and the resulting

penetrates the nervous system, but that neither thimerosal nor ethyl mercury, can cross the blood-brain barrier) (citations omitted).

80. *Cedillo*, 2009 WL 331968, at *19. It is worth noting that in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 583 (1993), the Supreme Court also explored the differences between expert opinions based on *in vitro* and *in vivo* studies demonstrating the teratogenic properties of the anti-nausea drug Bendectin.

81. *Cedillo*, 2009 WL 331968, at *19.

82. *See id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.* at *23.

lengthy decisions are replete with detailed assessments of the scientific validity of each competing theory and claim. The new cases received significant media attention when they were published and are easily accessible on the Internet. They are also accessible via new vaccine advocacy websites that include ecbt.org and vaccinateyourbaby.org, which feature Amanda Peet as their celebrity spokesperson.⁸⁷

III. FROM THE BOTTOM-UP: WILL THE FEDERAL VACCINE COURT CASES CHANGE GRASSROOTS DECISION MAKING?

The Federal Vaccine Court's assessments and conclusions could change behavior from the bottom-up by stemming the tide of vaccine refusals. This would reflect a social shift toward greater reliance on "[p]rofessional knowledge of immunization [that] is grounded in science—microbiology, immunology, epidemiology, and statistics."⁸⁸ The three cases are so new that we can predict, but not yet measure, their social impact in the United States and abroad. As a preliminary matter, changes in grassroots behavior are more likely if the cases are understood as a new addition to a developing body of legitimate scientific information.

A. *Will Future Decisions Be Based on the Developing Body of Scientific Knowledge?*

1. *Evaluating the Epistemological Data*

What we know today about competing scientific claims regarding the link between vaccines and autism should be informed by existing epidemiological evidence. After Dr. Wakefield's study was published, several research groups around the world conducted controlled observational studies to determine whether they could find evidence to support Dr. Wakefield's claims.⁸⁹ Of the fourteen separate epidemiological studies, *not one* found any association between MMR vaccines and autism.⁹⁰ In an effort to encourage grassroots fact-based decision making about vaccines, groups such as the Centers for Disease Control and Prevention, the Food and Drug Administration, the Institute of

87. See Childs, *supra* note 71.

88. Judelsohn, *supra* note 46.

89. See *id.*

90. See generally *id.*

Medicine, the World Health Organization, and the American Academy of Pediatrics provide information about these studies to the public.⁹¹

2. *Investigating the Proponents of the Link Between MMR Vaccines and Autism*

The body of public knowledge about vaccine safety has also been shaped by the work of investigative journalists. For example, *New York Times* science reporters Gardiner Harris and Anahad O'Connor have analyzed the work of Dr. Mark Geier and his son David, who are prominent proponents of the claim that MMR vaccines cause autism.⁹² These journalists discovered that Dr. Geier (who has served as a plaintiffs' expert witness in over ninety cases against vaccine manufacturers) conducts his experiments in the basement of his suburban Maryland home.⁹³ They have also reported that a judge presiding over one of the cases in which he served as an expert referred to him (on the record) as "a professional witness in areas for which he has no training, expertise and experience," and that others in his field consider his purported research to be "uninterpretable" and "voodoo science."⁹⁴ Special Master Vowell, in an earlier Federal Vaccine Court decision, found "articles authored by Dr. Geier unpersuasive and not scientifically sound . . . [and] my fellow special masters and several other judges have opined unfavorably on his qualifications and testimony as an expert."⁹⁵

More recently, Brian Deer, an investigative reporter for London's *Sunday Times* has discovered that Dr. Andrew Wakefield misrepresented the results of his original 1998 study to create the appearance of a link between MMR vaccines and autism.⁹⁶ Mr. Deer has also uncovered evidence that Dr. Wakefield received significant financial support from plaintiffs' counsel engaged in

91. Moreno, *supra* note 1, at 414.

92. See, e.g., Harris & O'Connor, *supra* note 13.

93. *Id.*

94. *Id.*

95. Doe/03 v. Sec'y of Dep't Health & Human Servs., 2007 WL 2350645, at *3 (Fed Cl. July 31, 2007).

96. Brian Deer, *Hidden Records Show MMR Truth*, SUNDAY TIMES (LONDON), Feb. 8, 2009, at 6, available at http://www.timesonline.co.uk/tol/life_and_style/health/article5683643.ece [hereinafter Deer, *Hidden Records*]. The controversy surrounding Dr. Wakefield's work has received significant public attention. See Begley, *supra* note 43.

lawsuits against vaccine manufacturers.⁹⁷ Mr. Deer also reported that, at the time of his 1998 article, Dr. Wakefield had a pending patent application for his own MMR vaccine.⁹⁸ Dr. Paul Offit, in his recent book *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure*, reported ethical concerns about Dr. Wakefield's study.⁹⁹ According to Dr. Offit, Dr. Wakefield's experiments on children (which included general anesthesia, spinal taps, and intestinal biopsies) were never approved by the hospital's ethics committee.¹⁰⁰ These reports led *The Lancet* to retract Dr. Wakefield's study and he currently faces charges of professional misconduct in the United Kingdom.¹⁰¹ On February 11, 2009, Keith Olbermann of MSNBC joined the fray, naming Dr. Wakefield "the worst person in the world" based on his almost single-handed responsibility for the worldwide paranoia that discourages parents from getting the MMR vaccine for their children, which puts millions of children around the world at risk for measles, mumps, and rubella.¹⁰²

B. *Are Public Health Concerns Globalized?*

To the extent that healthcare is increasingly conceptualized as global, decision makers may be more likely to weigh the international public health costs associated with vaccine shunning. Global concerns can impact micro-level decisions because the ease and frequency of foreign travel makes individual contact with people from other countries much more likely. At a macro level, increased vaccine refusals in developing countries are much more likely to cause children to die from vaccine-preventable diseases.¹⁰³ Vaccine avoidance also creates incentives for vaccine companies to curtail the use of preservatives, which limits packaging options. If

97. Deer, *Hidden Records*, *supra* note 96, at 6.

98. See Brian Deer, *How a Spurious Health Scare Brought an Old Killer Back*, SUNDAY TIMES (LONDON), June 18, 2006, at 13, available at <http://www.timesonline.co.uk/tol/news/uk/article676040.ece>.

99. PAUL A. OFFIT, *AUTISM'S FALSE PROFITS* 37–38 (2008).

100. *Id.*

101. See Deer, *Hidden Records*, *supra* note 96.

102. *Countdown with Keith Olbermann* (MSNBC television broadcast Feb. 10, 2009), transcript available at <http://www.msnbc.msn.com/id/29137822>.

103. See, e.g., *Unacceptably High Mortality Related to Measles Epidemics in Niger, Nigeria, and Chad*, PLOS MED., Jan. 2, 2007, <http://ukpmc.ac.uk/articlerender.cgi?artid=874564> ("Children in these countries still face an unacceptably high risk of death from a completely preventable disease. Much more needs to be done to increase the number of children who are vaccinated.").

developing countries are forced to bear the much greater cost of paying for single-dose vaccine packaging, vital childhood immunization programs could become prohibitively expensive. Privately funded programs, like the Children's Vaccine Program, a project of the Bill & Melinda Gates Foundation, play a vital global financial role.¹⁰⁴ However, these groups have been increasingly forced to devote scarce time, money, and attention to dispelling persistent speculation about vaccine safety.¹⁰⁵ Unfortunately, these messages are frequently ineffective. We are currently seeing outbreaks of vaccine-preventable diseases like polio that we once believed were eradicated.¹⁰⁶

C. How Can the Grassroots/Bottom-Up Impact of the New Federal Vaccine Court Cases Be Measured?

The ongoing trend of vaccine shunning suggests that bad thinking about the dangers of childhood vaccinations will need to be corrected before decision-making behaviors will change. Just six months before the new cases were announced, the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention reported that the national incidence of measles doubled from the previous year.¹⁰⁷ The Center's director, Dr. Anne Schuchat, attributed these new outbreaks to communities of underimmunized children whose

104. See PATH, PATH'S CHILDREN'S VACCINE PROGRAM (2004), http://www.path.org/vaccineresources/files/CVP_Global.pdf.

105. For example, the World Health Organization issued the following statement as part of its decade-long effort to prevent the public from mistakenly assuming that thimerisol ever contained methyl mercury:

In 1999, concerns were raised in the United States about exposure to mercury following immunization. This was based on the realization that the cumulative amount of mercury in the infant immunization schedule potentially exceeded the recommended threshold set by the United States government for methyl mercury. However thimerisol, the preservative in some vaccines, contains ethyl mercury not methyl mercury.

GLOBAL ADVISORY COMM. ON VACCINE SAFETY, WORLD HEALTH ORG., STATEMENT ON THIOMERSAL (July 2006), http://www.who.int/vaccine_safety/topics/thiomersal/statement_jul2006/en/index.html.

106. See World Health Organization, Polio Case Count, http://www.who.int/immunization_monitoring/en/diseases/poliomyelitis/case_count.cfm (last visited May 8, 2009). See also Anna Borzello, *Nigeria's Muslim Clerics Fear Polio Vaccine*, BBC NEWS, Jan. 16, 2004, <http://news.bbc.co.uk/2/low/africa/3400651.stm>.

107. Rong-Gong Lin II, *Rise in Measles Prompts Concern*, L.A. TIMES, May 2, 2008, at 1.

parents obtained “personal belief” vaccine exemptions to attend public school.¹⁰⁸ This assumption is supported by the fact that 98% of the children who contracted measles between 2007 and 2008 had never been immunized.¹⁰⁹ Over the past two years, more than twelve thousand unvaccinated European children have been diagnosed with measles.¹¹⁰

According to Dr. Paul Offit, these are predictable social behavior trends because “[a]s you start to see an erosion of confidence in vaccines and . . . pockets of people choosing not to vaccinate, this is what you’ll see. . . . Measles is not eliminated from the world.”¹¹¹ The new Federal Vaccine Court cases contain a careful synthesis of the available scientific evidence that is easily accessible to the public. Vaccine compliance records and disease outbreak data will eventually reveal whether these science-based legal decisions can shift grassroots behavior by encouraging greater reliance on legitimate scientific information.

IV. FROM THE TOP-DOWN: WILL THE FEDERAL VACCINE COURT CASES ENCOURAGE MORE ACCURATE EVALUATION OF COMPETING SCIENTIFIC CLAIMS?

According to Justice Breyer, “[t]he legal disputes before us increasingly involve the principles and tools of science.”¹¹² Courts, policymakers, and scholars who endeavor to guide the development of law can generate top-down shifts in attitudes and social behavior. For almost two decades, the science and law canon has been dominated by evidence scholars engaged in post-*Daubert* explorations of the judicial operation of scientific evidence admissibility standards in a range of factual contexts designed to guide future courts (e.g., fingerprint matching, ballistics comparison, lie detection, DNA analysis). Evidence scholars interested in a more direct role in shaping future science-based legal decisions have developed a network of “science for judges”

108. *Id.*

109. *Id.* (“Of the 64 [children] who have fallen ill in the United States this year, 63 had no records of vaccination.”).

110. Michelle Fay Cortez, *Measles Spreading in European Children as Parents Shun Vaccine*, BLOOMBERG.COM, Jan. 7, 2009, <http://www.bloomberg.com/apps/news?pid=20601085&sid=aa6EwXxFn0Do&refer=europe>.

111. Lin, *supra* note 107, at 2.

112. Stephen Breyer, *Introduction* to REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 2 (2d ed. 2000).

programs.¹¹³ These programs train federal and state judges to better understand and apply basic scientific methods and principles when they decide to admit or exclude proffered expert evidence.¹¹⁴

The new Federal Vaccine Court cases involve thorough and detailed judicial explorations of complex scientific evidence. It might be logical to assume that these cases should be incorporated into the developing science and law canon so that they can contribute to future judicial and scholarly analyses and guide those who must choose among competing scientific claims and theories. But the Federal Vaccine Court cases *do not* involve the application of evidence rules or standards. Thus, the potential top-down impact of these cases on how scholars (and perhaps judges) think about science and law will be constrained by a *Daubert*-driven conceptualization of “science and law.” Our current view of the field tends to adhere to rigid disciplinary boundaries and ignore even the most relevant and useful science-based legal analyses if they arise in other (non-evidence) fields and contexts.

A. *The “Daubert Revolution:” Daubert v. Merrell Dow Pharmaceuticals, Inc.*

In 1993, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court reversed a century of judicial deference to scientific experts.¹¹⁵ *Daubert*, with its conclusion that in the future judges would need to gatekeep the admission of scientific evidence, embodied the Court’s response to well-publicized concerns that courts were both too receptive to specious science and too inclined to reject novel (but valid) science.¹¹⁶ *Daubert* would solve both of these problems by encouraging judges to familiarize themselves with basic scientific ideas and methods and by providing flexible but specific scientific validity criteria (i.e., falsifiability, error rates, peer review and publication, and general acceptance) for courts to

113. See Margaret A. Berger, *Science for Judges*, 12 J.L. & POL’Y 1 (2003).

114. *Id.*

115. 509 U.S. 597 (1993).

116. See Haack, *Of Truth*, *supra* note 21, at 990 (noting that “the ostensible intent of the *Daubert* ruling was to relax the ‘austere standard’ of the older Frye rule in accordance with FRE 702”); Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 1 (1995) (describing *Daubert* as a response to critics of the tort system who complained that “leniency in admitting scientific expert testimony, especially in mass exposure litigation. . . . [has] resulted in an epidemic of ‘junk science’”).

use when making future admissibility determinations.¹¹⁷

Over the next five years, in the two remaining “*Daubert* Trilogy” cases, the Supreme Court clarified that these evidentiary rulings should be subject to an abuse of discretion standard of review.¹¹⁸ The Court also expanded *Daubert*'s gatekeeping requirement to include technical and other forms of specialized expert evidence.¹¹⁹ In late 2000, Federal Rule of Evidence 702 was amended to codify these doctrinal clarifications.¹²⁰

In the post-*Daubert* era, *Daubertista* evidence scholars have generated a series of often thoughtful and well-substantiated critiques of countless forms of scientific evidence (especially forensic science evidence). These analyses have effectively drawn legal and public attention to the problems that arise when evidence standards are ignored or improperly applied, and have had both theoretical and practical application. Many of the DNA exonerations achieved by the Innocence Project, for example, have links to *Daubertista* research into the types of specious science introduced by prosecutors during trials that resulted in false convictions.¹²¹ *Daubertistas* can also properly take much of the credit for the National Academy of Sciences (“NAS”) report, *Strengthening Forensic Science in the United States: A Path Forward*, released in February 2009.¹²² This new NAS report validates many longstanding *Daubertista* concerns including: (1) the reliability of many types of forensic evidence; (2) quality control among the

117. *Daubert*, 509 U.S. 597 (1993).

118. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997).

119. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (holding that the *Daubert* gatekeeping role “applies not only to [expert] testimony based on ‘scientific’ knowledge, but also to testimony based on ‘technical’ and ‘other specialized’ knowledge”).

120. The December 2000 modifications to Federal Rule of Evidence 702, Testimony by Experts, appears below in italics:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, *if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.*

FED. R. EVID. 702 (emphasis added).

121. See Innocence Project, <http://www.innocenceproject.org> (last visited May 8, 2009).

122. NATIONAL RESEARCH COUNCIL, STRENGTHENING FORENSIC SCIENCE IN THE UNITED STATES: A PATH FORWARD (2009), http://books.nap.edu/openbook.php?record_id=12589&page=R1.

nation's crime labs; and (3) problems of expert witness bias.¹²³ The practice implications of these findings are significant and could lead to systemic innovation and improvement. However, the tight *Daubertista* focus on evidence standards too often fails to recognize and incorporate relevant and useful developments from other fields and disciplines.

B. Can a Daubertista Approach to Science and Law Accommodate Insights from the Federal Vaccine Court Cases?

The Federal Vaccine Court cases did *not* involve traditional “science and law” evidence questions. If the past is predictive, these new cases will be read narrowly. They will likely control subsequent civil actions based on claims that MMR vaccines caused autism. However, guidance about science-based legal decisionmaking derived from these cases may not be generalized.

These concerns are not purely speculative. By any reasonable measure, the most important science-based legal decision from the federal courts over the past few years was *Kitzmiller v. Dover Area School District*.¹²⁴ *Kitzmiller*, like the new Federal Vaccine Court cases, involved complex and high-profile competing scientific theories and claims. A brief review of *Kitzmiller* illustrates some of the systemic obstacles to top-down shifts in attitudes and behavior.

1. Kitzmiller: Evaluating the Competing Scientific Claims of Evolution and Intelligent Design Theory

It is hard to fathom two more closely related inquiries than Justice Blackmun's effort to identify the attributes of legitimate science in *Daubert* and Judge John E. Jones, III's recent exploration of the scientific underpinnings of Intelligent Design Theory in *Kitzmiller v. Dover Area School District*.¹²⁵ In *Kitzmiller*, Judge Jones addressed the constitutionality of a local school board requirement that all public high school science teachers read a statement to their biology classes that included the following:

Because Darwin's Theory is a theory, it continues to be tested as new evidence is discovered. The Theory is not a

123. *See id.*

124. *See* Jay D. Wexler, Symposium, *Kitzmiller and the “Is It Science?” Question*, 5 FIRST AMEND. L. REV. 90, 92 (2006) (stating that the “clear, painstakingly documented” decision was a strong victory for opponents of ID).

125. 400 F. Supp. 2d 707 (M.D. Pa. 2005).

fact. Gaps in the Theory exist for which there is no evidence. A theory is defined as a well-tested explanation that unifies a broad range of observations.

Intelligent Design is an explanation of the origin of life that differs from Darwin's view. The reference book, *Of Pandas and People*, is available for students who might be interested in gaining an understanding of what Intelligent Design actually involves.¹²⁶

The *Kitzmiller* case has been aptly described as the first time that: [T]he intelligent-design movement as a whole stood trial on the claim that they were trying to pass off a religious view as though it were a *scientific theory*, so that they could market it to students in public-school science classrooms. They defended themselves by saying that they were doing nothing dishonest, much less unconstitutional, because intelligent design is a *scientific theory* that belongs in science classes.¹²⁷

After an eight-week trial that included the presentation of extensive evidence from both parties, Judge Jones held that the school board policy violated the Establishment Clause.¹²⁸

2. *The Kitzmiller Court Describes What Is, and What Is Not, Science*

Kitzmiller was an Establishment Clause case. Thus, Judge Jones could have easily avoided the epistemological morass of the “what is science?” debate.¹²⁹ Instead he decided that it was “incumbent upon the Court to . . . address an additional issue raised by Plaintiffs, which is whether ID is science.”¹³⁰ Judge Jones acknowledged that “answering this question compels us to revisit evidence that is entirely complex, if not obtuse . . . and include[s] countless hours of detailed expert witness presentations”¹³¹

126. *Id.* at 708–09.

127. Richard B. Katskee, Symposium, *Why It Mattered to Dover that Intelligent Design Isn't Science*, 5 FIRST AMEND. L. REV. 112, 112 (2006) (emphasis added).

128. *Kitzmiller*, 400 F. Supp. 2d at 765.

129. In fact, Professor Jay Wexler has argued that Judge Jones should not have undertaken this inquiry. “[T]he important issue for evaluating the [*Kitzmiller*] decision is not whether ID actually is science—a question that sounds in philosophy of science—but rather whether judges should be deciding in their written opinions that ID is or is not science as a matter of law.” Wexler, *supra* note 124, at 93.

130. *Kitzmiller*, 400 F. Supp. 2d at 734.

131. *Id.* at 735.

However, the *Kitzmiller* court viewed this as an essential obligation that transcended the need to resolve the instant case. According to Judge Jones:

[T]he Court is confident that no other tribunal in the United States is in a better position than are we to traipse into this controversial area. Finally, we will offer our conclusion on whether ID is science not just because it is essential to our holding that an Establishment Clause violation has occurred in this case, but also in the hope that it may prevent the obvious waste of judicial and other resources which would be occasioned by a subsequent trial involving the precise question which is before us.¹³²

Thus, Judges Jones wrote broadly and for posterity when he devoted a substantial portion of his 139-page opinion to a detailed and explicit description of how and why Intelligent Design could *never* be legitimate science.¹³³

Kitzmiller, like the Federal Vaccine Court cases, provides important and useful guidance for courts that must choose accurately among competing scientific claims. For example, the *Kitzmiller* court explained that legitimate science can be identified by the scope of its claims because science is “limited to empirical, observable and ultimately testable data.”¹³⁴ According to Judge Jones, science can also be distinguished from pseudoscience, because pseudoscience is often marked by a tendency to “attribut[e] unsolved problems about nature to causes and forces that lie outside the natural world [which] is a ‘*science stopper*.’”¹³⁵ The *Kitzmiller* court further demonstrated how future courts can accurately identify genuine areas of scientific agreement by determining whether claims and theories have been subjected to peer review and published in peer-reviewed journals.¹³⁶ In a second unattributed nod to *Daubert*, Judge Jones described falsifiability as an essential component of all legitimate scientific theories.¹³⁷ He also explained that the validity of a scientific theory, like Darwin’s theory of evolution, is not threatened by criticism that it is

132. *Id.*

133. See Wexler, *supra* note 124, at 100–03 (arguing that Judge Jones overstepped his judicial obligations by determining whether ID is science).

134. *Kitzmiller*, 400 F. Supp. 2d at 735.

135. *Id.* at 736 (emphasis added).

136. See *id.* at 735 (noting that ID has not been accepted by the scientific community or discussed in any peer-reviewed journals).

137. *Id.* at 717.

“imperfect” or incomplete.¹³⁸ According to Judges Jones, “the fact that a scientific theory cannot yet render an explanation on every point should not be used as a pretext to thrust an untestable alternative hypothesis . . . into the science classroom or to misrepresent well-established scientific propositions.”¹³⁹ Finally, Judge Jones concluded that pseudoscientific claims and critiques, like those advanced by the Intelligent Design Movement, can *never* be science because they are simply “not testable by the methods of science.”¹⁴⁰

Kitzmiller was decided in the spotlight of the national media. Judge Jones addressed a science-based legal question of continuing importance.¹⁴¹ The scientific question was explained in plain but detailed language aimed at future top-down decision makers including judges, politicians, and local school board members.

3. *The Kitzmiller Case is Excluded from the Daubertista Science and Law Canon*

After *Kitzmiller* was decided in December 2005, it seemed to contain the seeds of change. In fact, the *Kitzmiller* court spoke directly to the fundamental science and law concerns that had long preoccupied *Daubertista* scholars. More than three years later, *Kitzmiller* has had little or no impact on the field. With just a few notable exceptions,¹⁴² the science and law implications of *Kitzmiller* have been generally ignored.¹⁴³

138. *Id.* at 765.

139. *Id.*

140. *Id.* at 737.

141. In 2008, Louisiana enacted a new statute that allows public school science teachers to critique “controversial” scientific theories like evolution. See Adam Nossiter, *Boycott by Science Group Over Louisiana Law Seen as Door to Teaching Creationism*, N.Y. TIMES, Feb. 16, 2009, at A14.

142. *Kitzmiller* has not been entirely ignored. For example, Richard B. Katskee, Assistant Legal Director for Separation of Church and State and plaintiffs’ counsel in *Kitzmiller*, examined the importance of Judge Jones’ decision that Intelligent Design could not be science in the context of a recent forum on religion in the public schools. Katskee, *supra* note 127, at 116 (supporting and defending Judge Jones’ choice to determine whether ID is science). See also Susan Haack, *What’s Wrong with Litigation-Driven Science? An Essay in Legal Epistemology*, 38 SETON HALL L. REV. 1053, 1071–72 (2008) [hereinafter Haack, *Essay in Legal Epistemology*] (commenting on the legal implications of considering whether ID is science); Wexler, *supra* note 124, at 93 (warning that the *Kitzmiller* decision is problematic because the consideration of what consists of science should be separate from judicial decisions).

143. In a completely informal effort to understand why *Kitzmiller* failed to fulfill

C. *Why the Federal Vaccine Court Cases and Kitzmiller Suggest that We Need a More Inclusive and Transdisciplinary Approach to Science and Law*

1. *The Limits of the Judge as Gatekeeper Model*

Daubert provoked almost two decades of responsive *Daubertista* scholarship focused on the Supreme Court's new designation of the judge as a scientific evidence *gatekeeper*.¹⁴⁴ Justice Blackmun's characterization of a judge as a type of gatekeeper is of course accurate; judges exercise quality control over the evidence that they decide to admit at trial. The analogy of judging to gatekeeping may feel especially apt to evidence scholars who tend to focus much of their attention on the operation of admissibility rules and standards. The problem with envisioning the judge as a gatekeeper of science is that gatekeepers have just one (rather menial) job. They monitor what comes *in* the gate. This problem has never been addressed or explored within the *Daubertista* science and law canon despite the fact that, at a practical level, this is a limited and unrealistic description of what judges actually do. Of course judges are responsible for what happens at trial, but we cannot reasonably expect judges to wholly ignore the broader top-down implications of their decisions—especially their decisions about science.

Law does not happen in a vacuum. The idea that gatekeeping judges reflect on only the case-specific in-court impact of proffered scientific claims and theories ignores the real world outside the courthouse, the fact that information about science-based legal issues also travels from the bottom-up, and the genuine interdependence of law, science, and society. It is inarguable that judges must focus on the specific facts and issues in each case and

its promise to inform the field, I asked evidence professor participants at the June 2008 Association of American Law Schools Midyear Evidence Conference (a conference that devoted significant time and attention to science and law matters) why *Kitzmiller* played such an insignificant role. Their responses were consistent. Colleagues either express unfamiliarity with the case or their view that it had little bearing based on its Establishment Clause context. If cases like *Kitzmiller* and the Federal Vaccine Court cases that offer relevant and useful insight on how law should evaluate scientific information fall outside the boundaries of the science and law field, perhaps it is time to rethink where we have staked those boundaries.

144. See Wexler, *supra* note, 124, at 105 (stating that some have argued that *Daubert* requires federal judges to determine whether evidence is scientific before allowing it as evidence).

the application of proffered scientific evidence to these facts.¹⁴⁵ But, as Justice Breyer observed, this type of perpetual *Daubertista* focus is an incomplete description of the judicial task because “[t]he importance of scientific accuracy in the decision of such [science-based] cases reaches well beyond the case itself.”¹⁴⁶ When Judge Jones expressed his hope that *Kitzmiller* “may prevent the obvious waste of judicial and other resources which would be occasioned by a subsequent trial involving the precise question which is before us,”¹⁴⁷ he was simply acknowledging the well-known fact that science-based legal decisions have the power to transcend their individual cases and contexts. According to Justice Breyer, judges know that their decisions have ramifications beyond the courthouse gate because:

A decision wrongly denying compensation in a toxic substance case . . . can not only deprive the plaintiff of warranted compensation but also discourage other similarly situated individuals from even trying to obtain compensation and encourage the continued use of a dangerous substance. On the other hand, a decision wrongly granting compensation, although of immediate benefit to the plaintiff, [through the strong financial disincentives that accompany a finding of tort liability,] can improperly force abandonment of the substance. Thus, if the decision is wrong, it will improperly deprive the public of what can be far more important benefits—those surrounding a drug that cures many while subjecting a few to less serious risk, for example.¹⁴⁸

In Justice Breyer’s view, the significant interplay among law, science, and society means that we must embark on a “search for law that reflects an understanding of the relevant underlying science”¹⁴⁹ This search should transcend the narrow focus on gatekeeping perpetuated by sixteen years of *Daubertista* jurisprudence to incorporate useful and relevant insights from all science-based legal decisions.

145. In fact, I have previously argued that this was Justice Breyer’s intent in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). See generally Joëlle Anne Moreno, *Beyond the Polemic Against Junk Science: Navigating the Oceans that Divide Science and Law with Justice Breyer at the Helm*, 81 B.U. L. REV. 1033 (2001).

146. Breyer, *supra* note 112, at 3.

147. *Kitzmiller v. Dover Area Sch. Dist.*, 400 F. Supp. 2d 707, 735 (M.D. Pa. 2005).

148. Breyer, *supra* note 112, at 3–4.

149. *Id.* at 4.

V. CONCLUSION

It is awfully tempting to assume that a change in political parties and players that appears to be pro-science will resolve the problems of science-based decision making. There is ample evidence that the past eight years have been bad for science. In fact, “[t]he most notable characteristic of the Bush administration’s science policy has been the repeated distortion and suppression of scientific evidence in order to fit ideological preferences about how the world should be, rather than how it is.”¹⁵⁰ There is also evidence that the Obama administration appears inclined to follow a different path. For example, on March 9, 2009, President Obama signed an executive order lifting previous bans on embryonic stem cell research.¹⁵¹ This order was accompanied by a directive specifically targeted at federal agencies instructing them to restore “scientific integrity” to science-based policy decisions.¹⁵² These political developments encourage optimism about more accurate future top-down science policy decisions.

However, as the cases and controversies discussed in this article illustrate, good law will continue to depend on good science and there will continue to be serious systemic obstacles to accurate science-based legal decisions. There is no easy solution to these problems. But while scientists, philosophers, and theologians search for *truth*, judges and jurors must decide legal cases. After sixteen years, *Daubertsista* hegemony over the science and law field

150. Olivia Judson, Blog Post, *Back to Reality*, N.Y. TIMES, Dec. 2, 2008, <http://judson.blogs.nytimes.com/2008/12/02/back-to-reality>. See generally SETH SHULMAN, UNDERMINING SCIENCE: SUPPRESSION AND DISTORTION IN THE BUSH ADMINISTRATION (2008); CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE (2005).

151. Dan Vergano, *Obama Links Scientific Research to Protecting ‘Free Thinking,’* USA TODAY, Mar. 9, 2009, available at http://www.usatoday.com/news/washington/2009-03-08-obamastem_N.htm.

152. President Obama used the phrase “scientific integrity” to communicate to those concerned about both grassroots and top-down science-based decision making that the science policies of his administration would be different from those of his predecessor. Science policy has not been the most pressing problem confronting the new administration. However, at least in the area of climate change President Obama seems inclined to ensure that future policies are based on the facts. In a statement that accompanied his appointment of Stanford nuclear physicist and Nobelist Stephen Chu to head the Department of Energy, President Obama explained that Dr. Chu’s appointment “should send a signal to all that my administration will value science, we will make decisions based on the facts, and we understand and demand bold action.” See Joseph Romm, *Real Science Comes to Washington*, SALON, Jan. 26, 2009, http://www.salon.com/env/feature/2009/01/26/obama_cabinet/print.html.

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lead to a rather anemic approach that ignores relevant and useful developments simply because they arise in other fields or in non-evidence contexts. Science will shape law in new cases that will range from global climate change to intimate questions of reproductive choice. Sam Cooke honestly admitted that he “don’t know much biology;”¹⁵³ but neither do we and our wonderful world may depend on our ability to find new ways to learn more.

¹⁵³ SAM COOKE, *WONDERFUL WORLD* (RCA Records 1958).