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# WHAT ARE THE POLICY IMPLICATIONS OF USE OF EPIDEMIOLOGICAL EVIDENCE IN MASS TORTS AND PUBLIC HEALTH LITIGATION?

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## I. INTRODUCTION

Courts sometimes deal with public health problems where the cause of harm to one individual or a group of individuals cannot be established.[1] In such cases, epidemiology is used to help define a relationship which links the harm and the cause.[2] In mass tort cases, epidemiologic studies are used either to refute or to support claims involving an increased risk of disease from exposure to a toxic substance.[3] Consequently, how to use epidemiology when deciding mass tort cases is becoming an increasingly important question in public health law.[4] Courts use epidemiological

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1. *See* 63 AM. JUR. 2D *Products Liability* § 66 (1996) (describing epidemiology as an attempt "to define a relationship between a disease and a factor suspected of causing it").

2. *See id.*

3. *See* Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307, 311 (5th Cir. 1989); *see also* FED. JUDICIAL CTR., *Reference Guide on Epidemiology, in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 335–36 (2d ed. 2000) ("In the courtroom, epidemiologic research findings are offered to establish or dispute whether exposure to an agent caused a harmful effect or disease.").

4. *See, e.g.*, Pritchard v. Dow Agro Sciences, No. 07-1621, 2010 U.S. Dist. LEXIS 23098, at *33 (W.D. Pa. March 11, 2010). The court in *Pritchard* recently stated that "[g]eneral causation is often established in a toxic tort case through the use of epidemiological studies. 'Epidemiology is the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease.'" *Id.* (citing Soldo v. Sandoz

evidence to decide cases where a causal connection can be established between the exposure and the outcome.[5] In addition, courts use epidemiology for events that either have no "eyewitness or disproportionately involve certain types of products for which 'traditional' forms of evidence of causation are lacking."[6]

Recently, epidemiology has become a familiar form of proof in mass torts litigation, and those who are considered epidemiologists are often sought as expert witnesses in these cases.[7] However, the necessary evidentiary requirement of epidemiology studies occasionally does not coincide well with the basic principles of causation in tort law.[8] For example, even when presented with overwhelming epidemiological evidence, juries have sometimes returned a verdict for plaintiffs,[9] which indicates that some juries are not convinced by epidemiological evidence.

There are two imperative questions here: (1) how does epidemiology affect mass tort litigation; and (2) what relative weight should the courts give to epidemiological evidence? These questions are particularly significant in the area of causation. In order to establish causation, the plaintiff must demonstrate that it is "more probable than not" that the harm being complained of would not have occurred had the defendant followed the appropriate standard of care.[10] From prior case law, courts have derived rules for causation, namely the "but for" test and the "substantial factor test."[11] Under the first test, the defendant's conduct is deemed to be

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Pharm. Corp., 244 F. Supp. 2d 434, 532 (W.D. Pa. 2003)).

5. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 582 (1993).

6. Jon S. Vernick, Julie Samia Mair, Stephen P. Teret & Jason W. Sapsin, *Role of Litigation in Preventing Product-Related Injuries*, 25 EPIDEMIOLOGIC REV. 90, 93 (2003).

7. *See id.*

8. *See* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 284 (2000).

9. *Compare* Lynch v. Merrell-Nat'l Lab., 830 F.2d 1190, 1190–91, 1193–97 (1st Cir. 1987) (affirming the district court's finding of summary judgment in favor of the defendant because the epidemiological studies on Bendectin concluded tremendously that the drug does not cause birth defects), *with* Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 824–27 (D.C. Cir. 1988) (affirming a reversal of a jury award in favor of plaintiffs because the twenty years of epidemiological studies determined Bendectin does not cause birth defects), *and* Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307, 308 (5th Cir. 1989) (reversing a jury finding in favor of plaintiff because the great evidence established Bendectin does not cause birth defects). *See also* Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1159–64 (D.C. Cir. 1990) (upholding *Richardson* and reversing a jury finding in favor of plaintiff because of the overwhelming epidemiological studies that stated Bendectin does not cause birth defects).

10. *See* William Meadow & Cass R. Sunstein, *Causation in Tort: General Populations vs. Individual Cases* 2 (Univ. of Chi. Law & Econ., Olin Working Paper No. 360, 2007), *available at* http://www.law.uchicago.edu/files/files/360.pdf.

11. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 41, at 266–68 (5th ed. 1984).

a cause of the harm "if the [harm] would not have occurred but for that conduct."[12] However, under the second test, the defendant's conduct is a cause of the harm if that conduct was a substantial factor in producing the harm.[13]

The plaintiff bears the burden of proving causation, which is generally an issue of fact.[14] The plaintiff must introduce support indicating a reasonable basis for the conclusion that the defendant's conduct was "more likely than not . . . a cause in fact" of the outcome.[15] However, courts do not require the plaintiff to establish the case beyond a reasonable doubt.[16] The plaintiff need not entirely negate the possibility that something other than the defendant's conduct caused the harm.[17] It is sufficient for the plaintiff to introduce evidence from which a reasonable person may conclude that it is more probable than not that the defendant caused the event.[18] The preceding standard is generally known as the preponderance of the evidence standard, which means that it must be greater than fifty percent.[19] Unlike traditional tort law, which follows the preponderance of the evidence standard, epidemiology relies on statistical significance and is not necessarily based on the greater half of the evidence.[20] In public health litigation, for example, statistical evidence based on aggregate data is sometimes introduced to show that the defendants created a statistically significant increase in the likelihood that the harm would occur.[21]

For instance, in *General Electric Co. v. Joiner*, the United States Supreme Court held that the district court did not abuse its discretion when it excluded expert scientific testimony proffered by the plaintiff, an electrician, as evidence that his cancer resulted from exposure to polychlorinated biphenyls ("PCBs").[22] The plaintiff attempted to prove causation by introducing epidemiological studies involving workers who had been exposed to PCBs and experienced a statistically significant increase in lung cancer deaths, especially where the workers had been

12. *See id.* at 266. *But cf. id.* (distinguishing the but for test by explaining that the defendant would not be the cause of the event if it would have happened without the defendant's conduct).

13. *See id.* § 42, at 278.

14. *See id.* § 41, at 263–64, 269.

15. *Id.* at 269. *But see id.* (explaining that a mere likelihood of a causation of this nature is not sufficient for the test).

16. *See id.* at 269.

17. *See* KEETON ET AL., *supra* note 11, at 269.

18. *See id.*

19. *See id.* § 38, at 239.

20. *See* GOSTIN, *supra* note 8, at 284.

21. *See id.* at 284–86.

22. 522 U.S. 136, 146–47 (1997).

exposed to numerous potential carcinogens.[23] The plaintiff relied on four epidemiological studies.[24] However, the studies were not a sufficient basis for the experts' opinions.[25]

To begin with, from the workers they examined, the authors were ultimately unwilling to suggest a link between the increase in lung cancer deaths and the PCB exposure.[26] Moreover, the third study involved exposure to a particular type of mineral oil which was not necessarily relevant to the case, and the fourth study involved exposure to numerous other potential carcinogens.[27] Had the plaintiff used the preponderance of the evidence standard, the possibility that something other than the defendant's conduct caused the harm would not have to have been entirely negated; rather, it would have been enough for the plaintiff to have introduced evidence from which a reasonable person could have concluded it was more probable than not that the defendant caused the event.[28] Here, the epidemiological standard and the legal standard diverged.

In distinguishing between the legal standard and the epidemiological standard, Professor Gostin wrote:

> While law seeks finality and closure, scientific inquiry is continuous; while law in civil litigation makes decisions by the preponderance of evidence (greater than 50 percent), science uses statistical significance (greater than 95 percent, with a confidence limit that does not include 1.0); while law follows an adversarial method, science embraces the experimental design (the "scientific" method); while legal evidence is testimonial, scientific evidence is empirical.[29]

The distinctions between the standards of proof employed in epidemiology and in law inform the central thesis of this paper. This analysis began by describing the role of epidemiology in mass torts and public health litigation.[30] It later argues that because mass torts cover such a wide area, there are several problems related to epidemiology in litigation, particularly scientific uncertainty and inconsistent factual claims.[31]

Part II discusses recent cases where epidemiological evidence was raised and debated, distinguishing between vaccine-related and non-

23. *Id.* at 145–46.
24. *Id.* at 144.
25. *Id.* at 145.
26. *Id.*
27. *Id.* at 145–46.
28. *See* KEETON ET AL., *supra* note 11, at 269.
29. GOSTIN, *supra* note 8, at 282–83.
30. *See supra* text and accompanying notes 1–29.
31. *See* discussion *infra* Part I.A.

vaccine-related cases.[32] Courts have differentiated vaccine-related cases from non-vaccine-related cases, principally because Congress enacted a vaccine act designed to compensate victims.[33] In both vaccine and non-vaccine related cases, the legal concepts of specific and general causation are extensively used.[34]

Part III examines the two legal concepts of general and specific causation in epidemiology and how courts have tried to balance the epidemiological causation standard with general torts principles.[35] Part IV analyzes how epidemiological evidence differs from other evidence in terms of the tensions it raises for the legal system, and argues that despite these tensions, courts still hold that causation must be shown by epidemiological evidence.[36] Part V discusses the policy implications of what gets used in court and argues that reliance on human studies, as the best evidence, may be misplaced since one cannot freely experiment on human beings.[37] This section also considers whether epidemiologists should get involved in policy issues, discussing two divergent schools of thought.[38]

The paper concludes by suggesting that although the presence of epidemiological evidence does not necessarily end the inquiry; where the evidence is available, it should be used only if the evidence meets a heightened standard.[39] The heightened standard argued for in this paper is a screening standard for admission that considers not only a doubling of the risk by the exposure, but also jury instructions that clearly inform the jury of the strengths and weaknesses of epidemiological studies.[40] The paper also calls for the American College of Epidemiology and the Council for State and Territorial Epidemiologists ("CSTE") to develop model guidelines for the use of epidemiological evidence in the courtroom.[41] These guidelines could mirror the public health law bench books developed for some states to refer to during public health emergencies.[42]

32. *See* discussion *infra* Part II.A–B.
33. *See infra* text and accompanying notes 59–65, 133–34.
34. *See infra* Part II.
35. *See* discussion *infra* Part III.
36. *See* discussion *infra* Part IV.
37. *See infra* text and accompanying notes 224–39.
38. *See infra* text and accompanying notes 240–44.
39. *See infra* Part VI.
40. *See infra* Part VI.
41. *See infra* Part VI.
42. *See infra* Part VI.

## A. PROBLEMS WITH MASS TORTS LITIGATION

Mass tort litigation could range from products liability and negligence claims to securities litigation, antitrust, and a variety of consumer claims.[43] Since mass tort litigation covers such a wide area, there are several problems including, but not limited to, scientific uncertainty, latent disease, and future claimants.[44] Epidemiologists are often able to predict with a reasonable level of certainty that some number of individuals within a specified group will contract a disease.[45] We, however, do not know with "certainty which individuals will contract the disease and how many of those individuals will sue when their injuries become manifest."[46]

A special committee on toxic tort litigation cited inconsistent factual claims in different proceedings as one of the big problems.[47] Inconsistent factual claims and scientific uncertainty often affect the accuracy of the epidemiological evidence.[48] For example, "the vast majority of potentially hazardous substances have not been subjected to epidemiological study, thus, creating an evidentiary gap of potential concern to the tort system."[49] Furthermore, courts hearing products liability cases have been struggling with the social allotment of risk, and issues of who should bear the burden of scientific uncertainty or controversy when discussing injured people or manufacturers of the products alleged to have caused those injuries.[50] Should the rules regulating the *tort* system place the responsibility for uncertainty about the risks of a product on the manufacturer who has placed the product in the market perhaps without sufficient warning or testing?[51] Or, should the system accept the conservative values of *epidemiology*, "whose internal disciplinary standards start with a

43. *See* THOMAS E. WILLGING, MASS TORTS PROBLEMS AND PROPOSALS. A REPORT TO THE MASS TORTS WORKING GROUP app. C at 8 (Jan. 1999), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/MassTApC.pdf/$file/MassTApC.pdf.

44. *See generally id.* (outlining problems in mass tort litigation, and proposing solutions to those problems).

45. *See id.*

46. *Id.*

47. *See* RICHARD D. KIRK, BARTHOLOMEW J. DALTON, EDWARD M. MCNALLY, ALLEN M. TERRELL, JR. & JEFFREY M. WEINER, SPECIAL COMMITTEE ON SUPERIOR COURT TOXIC TORT LITIGATION, REPORT AND RECOMMENDATIONS 12 (2008), *available at* http://pdfserver.amlaw.com/nlj/DelawareSpecial%20CommitteeReport.PDF.

48. *See* Mark Geistfeld, *Scientific Uncertainty and Causation in Tort Law*, 54 VAND. L. REV. 1011, 1012 (2001).

49. *Id.* at 1013.

50. *See* Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 335–36 (1999).

51. *See id.* at 336.

hypothesis of lack of risk, and demand stringent statistical proof of a doubling or tripling of the risk of a disease before entertaining the possibility of a causal association?"[52]

In terms of inconsistent factual claims, epidemiologists, like many other experts, tend to differ in their interpretations, analysis, and conclusions.[53] The burden of deciding which study is valid or invalid, therefore, falls upon the judges or the jury.[54] The problem here is that both the judges and the jury tend to lack scientific expertise in epidemiology and other scientific disciplines.[55] This was recognized by Judge Posner of the United States Court of Appeals for the Seventh Circuit when he remarked that "it is a daunting task for judges who do not have a scientific background (and most do not) to decide whether a scientist's testimony is real science or not."[56] Despite these problems, the use of epidemiology in mass tort and public health litigation has been growing as indicated by the cases below.[57]

## II. RECENT CASES WHERE EPIDEMIOLOGICAL EVIDENCE WAS DEBATED

### A. VACCINE RELATED CASES

A plethora of public health litigation has occurred in the area of vaccines.[58] In recognition of this, Congress, in 1986, enacted the National Vaccine Injury Compensation Program ("VICP"), a federal no-fault program designed to resolve an apparent crisis in liability regarding vaccines which threatened the continued availability of childhood vaccines nationwide.[59] The Vaccine Act provided that in order to qualify for compensation and other relief under the VICP, the injury could be established by either causation in fact or causation in law.[60] To receive

52. *Id.*

53. *See id.* at 343–47.

54. *See* Pritchard v. Dow Agro Sciences, No. 07-1621, 2010 WL 936767, at *3 (W. D. Pa. 2010) (noting that "[t]he district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury").

55. *See* Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996).

56. *Id.* at 318.

57. *See* discussion *infra* Parts II–V.

58. *See* U.S. COURT OF FEDERAL CLAIMS, OFFICE OF SPECIAL MASTERS, VACCINE PROGRAM BACKGROUND 1, http://www.uscfc.uscourts.gov/sites/default/files/vaccine_files/VICP_General_Background.pdf (last visited July 2, 2010) [hereinafter VACCINE PROGRAM BACKGROUND].

59. *See id.*

60. *See* Althen v. Sec'y of Dep't of Health & Human Servs., 58 Fed. Cl. 270, 280 (2003).

compensation, causation in law is to be established by proving:

> [O]ne of the vaccines, listed in the vaccine injury table at 42 U.S.C. § 300aa-14(a), was administered to a petitioner and the "first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths" of specific adverse medical conditions associated with the use of each vaccine and listed in the table occurred within a time period specified in the table.[61]

The VICP originally only covered vaccines used to prevent seven diseases—polio, rubella (German measles), mumps, diphtheria, tetanus, pertussis, and measles.[62] Afterward, "coverage was extended to four additional vaccines—hepatitis B, hemophilus influenza type b (Hib), varicella (chickenpox), and rotavirus."[63] Furthermore, the annual influenza (flu) vaccine became covered in July 2005.[64]

One of the hotly contested areas in vaccine cases has been the link between Thimerosal and autism.[65] "Despite overwhelming scientific evidence to the contrary, many parents still believe that Thimerosal causes autism."[66] For a long time, the medical and public health community, through several epidemiological studies, have maintained that there is no evidence establishing a link between vaccination and autism.[67] But that may have changed somewhat.

In *Poling v. Secretary of Health and Human Services*,[68] the medical personnel at the Division of Vaccine Injury Compensation ("DVIC") acknowledged that the vaccine a child received years back, "significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism and manifested as a regressive encephalopathy with features of autism spectrum disorder."[69] Moreover,

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61. *Id.*

62. *See* VACCINE PROGRAM BACKGROUND, *supra* note 58, at 1.

63. *Id.*

64. *See id.*

65. *See* U.S. COURT OF FEDERAL CLAIMS, OFFICE OF SPECIAL MASTERS, OMNIBUS AUTISM PROCEEDING, http://www.uscfc.uscourts.gov/omnibus-autism-proceeding (follow "Background Information" hyperlink) (last visited July 2, 2010).

66. Wendy Parmet, *Pandemic Vaccines- The Legal Landscape*, 362 N. ENGL J. Med. 1949, 1950 (2010).

67. *See, e.g.*, Brent Taylor et al., *Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association*, 353 THE LANCET 2026, 2026–29 (1999); Robert T. Chen & Frank DeStefano, *Vaccine Adverse Events: Causal or Coincidental?* 351 THE LANCET 611, 611–12 (1998) (discussing that immunizations are among the most important health concerns because they are given to millions of individuals).

68. No. 02-1466V, 2008 U.S. Claims LEXIS 167, at *1 (Fed. Cl. Apr. 10, 2008).

69. *Id.* at *4–5.

the child developed adverse reactions after a series of five immunizations including nine vaccines.[70] When the medical team evaluated the child, it observed deficits in the child's communication and social development.[71] Plaintiff's experts using both medical and epidemiological evidence argued that the vaccination had caused regression in the child's development, consistent with autism.[72]

In granting the compensation, the Secretary did not concede that childhood vaccines cause autism.[73] Rather, the Secretary concluded that the vaccines given to the child aggravated a pre-existing condition that then manifested as autism-like symptoms.[74] This case is rather unique, in the sense that the child had an underlying mitochondrial disorder.[75] In March 2010, the United States Supreme Court granted a petition for writ of certiorari to the United States Court of Appeals for the Third Circuit in a vaccine injury case entitled *Bruesewitz v. Wyeth*.[76] This perhaps signaled a move towards taking a second look at the liability of vaccine manufacturers. However, it is important to note that the issue in *Bruesewitz* was not whether the vaccine caused the injury, but whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of the Court and others, Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986,[77] preempts all vaccine design defects claims and whether the vaccine's side effects were unavoidable or not.[78]

Other vaccine related cases, such as *Gannon v. United States*,[79] have had different outcomes from the cases cited above. For example, in *Gannon*, the Third Circuit Court of Appeals found that the United States did not violate federal regulations concerning the licensing, testing and manufacture of live oral polio vaccine.[80] In that case, Mr. Gannon and his

70. *See* Claudia Wallis, *Case Study: Autism and Vaccines*, TIME, Mar. 10, 2008, *available at* http://www.time.com/time/health/article/0,8599,1721109,00.html.

71. *See id.*

72. *See Poling*, 2008 U.S. Claims LEXIS 167, at *6–8.

73. *See id.* at *4–5.

74. *See id.* at *4–6.

75. *See id.* at *4.

76. 130 S. Ct. 1734 (2010).

77. Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 provides that "no manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable . . ." 42 U.S.C. § 300aa-22(b)(1) (2009).

78. Petitioner's Brief for a Writ of Certiorari at i, Bruesewitz v. Wyeth, 130 S. Ct. 1734 (2010) (No. 09-152), 2009 WL 21973.

79. 292 F. App'x 170 (3d Cir. 2008).

80. *See id.* at 172–75.

wife "filed a personal injury action against the United States under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b) and 2671-2680, alleging that an oral polio vaccine ("OPV") Jamie Gannon received between 1973 and 1976 was contaminated with SV40, a simian virus found in both monkeys and humans."[81]

The Gannons claimed there was negligence on behalf of the government when it failed to prevent Lederle Laboratories from making the OPV available to the public.[82] The district court found in favor of the United States concluding that the Gannons failed, among other things, to demonstrate by a preponderance of the evidence that SV40 caused cancer.[83] Plaintiffs' expert testified that based on his review of relevant and reliable literature, it was his opinion to a "reasonable degree of scientific and medical certainty that SV40 plays a causal role in the subset of human tumors in which it has been frequently found, including brain tumors and medulloblastomas."[84] The United States called three experts to testify and each concluded that SV40 has not been shown to be a cause of human cancer, including medulloblastoma.[85] Weighing the epidemiological and biological evidence, the court found that plaintiffs' evidence did not satisfy the well-recognized and broadly accepted criteria for evaluating causation developed by scientists such as Sir Bradford Hill.[86] The Bradford Hill criteria consists of nine factors addressing the issue of causality: (1) analogy; (2) temporality; (3) biologic gradient; (4) consistency; (5) specificity; (6) experimental evidence; (7) plausibility; (8) coherence; and (9) strength of association.[87]

Furthermore, the *Gannon* Court relied upon the Institute of Medicine's ("IOM") 2002 report, which concluded that "the evidence is inadequate to accept or reject a causal relationship" between SV40 and cancer.[88] In affirming the lower court's ruling, the Third Circuit noted that "based upon the foregoing analysis and its thorough consideration of the record evidence we cannot say that the court clearly erred in its findings of fact or that it erred in concluding that the Gannons had not met their burden of proof on the issue of causation."[89]

81. *Id.* at 171.
82. *See id.*
83. *See* Gannon v. United States, 571 F. Supp. 2d 615, 641 (E.D. Pa. 2007)
84. *Id.* at 622.
85. *See id.* at 624–25.
86. *See id.* at 625–26.
87. *See id.* at 626.
88. *Id.* at 628.
89. Gannon v. United States, 292 F. App'x 170, 174 (3d Cir. 2008).

Here, both plaintiffs and defendant relied heavily on biological and epidemiological evidence. The tipping point was the inconclusive biological and epidemiological evidence. Regarding the evidence adduced, the district court stated:

> [E]pidemiological and biological evidence are key components to all well-recognized scientific frameworks that examine causation of human diseases. If either epidemiological or biological evidence fails to support a causal connection or is otherwise inconclusive, one cannot conclude with any degree of certainty that a pathogen such as a virus is the cause of a disease such as human cancer.[90]

The impact of *Gannon* on mass tort litigation may signal the end of the SV40 litigation, unless plaintiffs can prove specific causation using well-known epidemiologic and biological evidence. But other courts have held otherwise. For example, in *Watson v. Secretary of Department of Health and Human Services*,[91] the Court found that Ms. Watson had established, by a preponderance of the evidence, that the tetanus vaccine caused her Guillain-Barre Syndrome ("GBS").[92]

Ms. Watson alleged a vaccine-related injury, specifically GBS, after receiving a tetanus vaccine at Convenient Health Care in Waldorf, Maryland on July 28, 1994.[93] When she filed for compensation from the National Vaccine Injury Compensation Program, the Secretary recommended compensation be denied citing absence of medical expert report and critical medical reports.[94] Specifically, the Secretary argued that "evidence that the vaccine is capable of causing the disease, a correct temporal relationship, and absence of proof of an alternative cause are inadequate as a matter of law to prove actual causation."[95] The *Watson* Court disagreed.[96] In considering the strength of the epidemiological evidence proffered in the case on the issue of causation, it followed the standard set forth in *Stevens v. Secretary of Health and Human Services*.[97]

The court in *Watson* noted that:

> In *Stevens*, the court found that, in the absence of controlling epidemiological data, petitioners can satisfy their *prima facie* burden to establish by a preponderance of the evidence that the vaccine in

90. Gannon v. United States, 571 F. Supp. 2d 615, 624 (E.D. Pa. 2007).
91. No. 96-639V, 2001 WL 1682537, at *1 (Fed. Cl. Dec. 18, 2001).
92. *See id.* at *1.
93. *See id.*
94. *See id.* at *3.
95. *Id.* at *6.
96. *See id.* at *1.
97. *See Watson*, 2001 WL 1682537, at *12 (citing Stevens v. Sec'y of Dep't of Health & Human Servs., No. 99-594V, 2001 WL 387418, *23–26 (Fed. Cl. March 30, 2001)).

> question caused the injury alleged by meeting the following five criteria: (1) proof of medical plausibility; (2) proof of confirmation of the medical plausibility from the medical community and literature; (3) proof of an injury recognized by medical plausibility evidence and literature; (4) proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) proof of the elimination of other causes.[98]

The court agreed with Ms. Watson that she had satisfied these five prongs by a preponderance of the evidence.[99] In essence, what this court was saying is that scientific causation can be proved in a number of ways, and epidemiology is just one of them. Why the different result between two seemingly similar cases? The determining factor here seems to be the strength of the epidemiological evidence. Unlike the *Gannon* Court, which refused to consider inconclusive epidemiological evidence as determining causation,[100] the *Watson* Court was more accommodating when it cited the plaintiff's expert and stated that:

> Epidemiology can be used to show changes in risk of contracting a disease or condition by a member of a defined population as exposure to known causes rise or fall. Epidemiology *cannot* be used to disprove a causal relationship between two events (exposure and disease), but it can be used to demonstrate increased or decreased risk. In the total absence of epidemiological evidence, while the epidemiologist can say there is no epidemiological evidence of a causal relationship, *he cannot conclude that there is no relationship.*[101]

The *Watson* decision would be music to the ears of mass torts plaintiffs. Rather than relying on the strict scientific norm that causation be proven with epidemiological study,[102] *Watson* offers an alternative to demonstrate actual causation through circumstantial evidence.[103] But this can be problematic, especially in the quality or quantity of evidence necessary to establish causation. In *Watson,* the court used the *Stevens* standard.[104] But *Stevens* was abrogated by *Althen v. Secretary of*

98. *Id.* at *4 (citing *Stevens*, 2001 WL 387418, at *23–26).

99. *See id.* at *28.

100. *See* Gannon v. United States, 571 F. Supp. 2d 615, 640–41 (E.D. Pa. 2007) (discussing the problems with using epidemiological evidence to determine causation).

101. Watson v. Sec'y of Dep't of Health & Human Servs., No. 96-639V, 2001 WL 1682537, at *10 (Fed. Cl. Dec. 18, 2001).

102. *See* Andrew See, *Use of Epidemiology Studies in Proving Causation*, 67 DEF. COUNS. J. 478, 479 (2000), *available at* http://ruby.fgcu.edu/Courses/Twimberley/EpiRiskAsst/Causation.pdf (remarking that many courts have held that it is necessary to offer epidemiology evidence to prove causation).

103. *See Watson*, 2001 WL 1682537, at *12.

104. *See id.* at *1 (explaining that the court's findings were based upon the application of the causation criteria set forth in the *Stevens* decision); *see also id.* at *10 (stating the *Stevens*

*Department of Health and Human Services*,[105] which held that the application of the *Stevens* "analytical framework" contravened the Vaccine Act,[106] along with Supreme Court and Federal Circuit precedent.[107]

In *Althen*, plaintiff filed suit under the National Childhood Vaccine Act alleging that she suffered optic neuritis and acute-disseminated encephalomyelitis ("ADEM") as direct result of tetanus toxoid vaccination.[108] The lower court, using the *Stevens* framework, denied the claim.[109] On appeal, the Court of Federal Claims held that claimant established entitlement to relief under Vaccine Act, reasoning that "three of the five *Stevens* elements either significantly change[d] the statutory burden of proof or directly contravene[d] the language of the Vaccine Act and therefore . . . [were] erroneous as a matter of law."[110]

In affirming the Court of Federal Claims, the Court of Appeals held that a persuasive medical theory connecting a vaccination to an injury, for purposes of National Childhood Vaccine Act, "is demonstrated by 'proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]' the logical sequence being supported by 'reputable medical or scientific explanation[,]' *i.e.*, 'evidence in the form of scientific studies or expert medical testimony[.]'"[111] Here, the court reasoned that the Vaccine Injury Compensation Statute only requires that "a petitioner . . . prove causation in fact by a 'preponderance of the evidence,' substantiated by medical records *or* medical opinion, as to each factor contained in section 300aa-11(c)(1)."[112]

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standard).

105. Althen v. Sec'y of Dep't of Health & Human Servs., 58 Fed. Cl. 270 (2003).

106. *See id.* at 282–83.

107. *See id.* at 282–85.

108. *See* Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1276 (Fed. Cir. 2005); *see also Althen*, 58 Fed. Cl. at 272–75 (explaining the facts leading to plaintiff filing suit under the National Childhood Vaccine Act).

109. *See Althen*, 58 Fed. Cl. at 272.

110. *Id.* at 283.

111. *Althen*, 418 F.3d at 1278 (citing Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)); *see also* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-13 (2010) (setting forth the requirements for compensation under the Vaccine Act).

112. *Althen*, 418 F.3d at 1279 (emphasis added); *see also* 42 U.S.C. § 300aa-13(a)(1) (2010) providing in pertinent part that:

> Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole- (A) that the petitioner has demonstrated by *a preponderance of the evidence* the matters required in the petition by section 300aa–11(c)(1) of this title, and (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition. The special master or court may not make such a finding based on the claims of a petitioner alone,

This principle of proving causation by medical opinion was further buttressed by the same court in *Andreu ex rel. Andreu v. Secretary of Department of Health and Human Services.*[113] In that case, Enrique Andreu's parents brought suit challenging a special master's denial of their petition for compensation, under the National Childhood Vaccine Injury Act, for their son's seizure disorder allegedly caused by inoculation with diphtheria, whole-cell pertussis, and tetanus ("DPT") vaccine.[114] The parents provided medical experts who testified that there was no other explanation for Andreu's seizure disorder other than the DPT vaccination.[115] In reversing the Court of Federal Claims, which had affirmed the special master's ruling, the Court of Appeals held that "requiring 'epidemiologic studies or general acceptance in the scientific or medical communities impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.'"[116]

Another case that eschewed epidemiological standard of causation in favor of physicians' testimony was *Sulesky v. United States.*[117] In *Sulesky*, the court found that defendant's flu shot was the proximate cause of plaintiff contracting a disease and that plaintiff was entitled to recover damages for physical injuries, physical pain and suffering, mental anguish, reasonable and necessary medical expenses, even though epidemiological evidence showed that there was no causal link between the Flu vaccination and the disease contracted by the plaintiff.[118] Kathryn Sulesky, the plaintiff, had contracted Gullian-Barre Syndrome ("GBS") after she received a swine flu shot in 1976.[119] Sulesky received the shot during the course of the mass immunization program instituted and conducted by the government.[120] The judge relied on the testimony of the treating physicians and wrote that the epidemiological evidence offered by the government was not determinative on the issue of causation.[121]

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unsubstantiated by medical records or *by medical opinion.*

*Id.* (emphasis added).

113. *See* 569 F.3d 1367 (Fed. Cir. 2009).

114. *See id.* at 1370–71.

115. *See id.* at 1375–76.

116. *Id.* at 1378 (quoting Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325–26 (Fed. Cir. 2006)).

117. *See* 545 F. Supp. 426, 431 (S.D. W. Va. 1982).

118. *See id.* at 430–31.

119. *See id.* at 433.

120. *See id.* at 427.

121. *See id.* at 430.

The *Sulesky* Court stated:

> [F]urther realizing that epidemiological studies attempt to address the causative link between a disease and a given variable (in this instance the swine flu shot) by comparing the incidence of the disease in the population exposed to that given variable (attack rate) with the incidence of the disease in the unexposed population (background rate), this Court finds that none of the epidemiological studies introduced into evidence may be employed to establish the Plaintiffs' case by a preponderance of the evidence. On the other hand, neither do the studies disprove that the cause of Kathryn Sulesky's GBS was the swine flu shot which she received fourteen weeks before the onset of her GBS. Therefore, while the Court has found the testimony and documentary evidence of the epidemiologists extremely valuable, and while it is not rejected out of hand, the Court does find that expert epidemiological testimony is not determinative of the issue of causation in this case.[122]

It is not clear why some courts consider epidemiological evidence to be determinative while others do not. One reason for this inconsistency could be that different laws often require different amounts of scientific evidence and the strength of the association, usually measured by the relative risk, to convince the fact finder.[123] For example, a lesser degree of scientific certainty might be needed for eligibility for worker compensation because of the humanitarian nature of these laws and the fact that an employee accepting theses payments forgoes his or her right to sue for other damages.[124] Another reason could be that some courts choose to follow well-recognized and broadly accepted criteria for evaluating causation that have been developed by scientists, while others simply follow the preponderance of the evidence standard.

One commentator suggests that to bridge this gap, both scientists and lawyers need to appreciate the different purposes of their professions, and scientists need to understand that time limits imposed by the legal system alter the potential amount of scientific information that will be available when a case must be filed and a decision must be made.[125] Additionally, when commenting on a decision, it is incumbent on scientists to read the

122. *Id.*

123. *See* Joseph L. Gastwirth, *Epidemiology as Legal Evidence.* ENCYCLOPEDIA OF BIOSTATISTICS 1357–1361 (P. Armitage & T. Colton eds. 1998).

124. *See id.*

125. *See* Joseph L. Gastwirth, 54th Session of the Int'l Statistical Inst.: Forensic Statistics and Legal Reasoning (Aug. 15, 2003) (invited paper, Epidemiology as Legal Evidence), *available at* http://isi.cbs.nl/iamamember/CD1/abstracts/papers/3359.pdf (providing an outline of Gastwirth's paper, Epidemiology as Legal Evidence).

decision carefully and to examine all the studies it relied on.[126] Joseph Gastwirth observes that virtually no study is perfect, thus critics need to do more than point out a potential flaw, e.g., recall bias.[127] Critics need to demonstrate that it is substantial enough to alter the ultimate inference.[128] Science should progress over time. An association uncovered in an early study should be one of the main focuses of a following one so that the issue of multiple comparisons in a subsequent study is minimized.[129] Data on variables shown, in prior studies, to be related to the response under investigation should be collected in the future studies.[130]

While there is some appeal to these suggestions, they seem to focus more on the scientists than the judges and the juries. Whether the suggestions can eliminate the inconsistencies among the courts is a point of conjecture. What is certain is that epidemiology continues to raise tensions both in vaccine related and non-vaccine related cases.

## B. NON-VACCINE RELATED CASES

Courts have distinguished vaccine related cases from non-vaccine related ones. As mentioned above, the vaccine related cases are different in the sense that Congress enacted a specific vaccine act to compensate victims.[131] Furthermore, in vaccine related cases, compensation is limited to specific diseases listed on the vaccine injury table.[132] In non-vaccine related cases, however, there is no specific controlling statute.

Perhaps the most contested area in public health litigation outside of vaccines is tobacco litigation. In the 1950s and 1960s, medical evidence established the role of tobacco smoking in the causation of cancer.[133] In 1950, Richard Doll published a study which showed that there was a causal link between smoking and lung cancer.[134] In 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act, branding cigarette boxes

126. *See id.*

127. *See id.*

128. *See id.*

129. *See id.*

130. *See* Joseph L. Gastwirth, 54th Session of the Int'l Statistical Inst.: Forensic Statistics and Legal Reasoning (Aug, 15, 2003) (invited paper, Epidemiology as Legal Evidence), *available at* http://isi.cbs.nl/iamamember/CD1/abstracts/papers/3359.pdf.

131. *See* VACCINE PROGRAM BACKGROUND, *supra* note 58, at 1.

132. *See id.*

133. *See* DAVID F. GOLDSMITH & SUSAN G. ROSE, *Establishing Causation with Epidemiology*, *in* SCIENCE ON THE WITNESS STAND: EVALUATING SCIENTIFIC EVIDENCE IN LAW, ADJUDICATION AND POLICY 59 (Tee L. Guidotti and Susan G. Rose, eds., 2001).

134. *See* Richard Doll & A. Bradford Hill, *Smoking and Carcinoma of the Lung, Preliminary Report*, 2 BRIT. MED. J. 739, 739–48 (Sept. 30, 1950).

with the words "Caution: Cigarette Smoking May be Hazardous to Your Health."[135] Since then, several lawsuits in different states have been brought against tobacco companies. The vast majority of court rulings have been in favor of tobacco companies.[136]

Epidemiological studies have been used by both plaintiffs and defendants to bolster their cases. For example, in *Tompkin v. Phillip Morris USA, Inc.*,[137] the plaintiff sued the defendant tobacco companies alleging that her husband Tompkin died as a result of smoking cigarettes sold by the defendants.[138] The plaintiff asserted statutory and common-law products liability claims.[139] At trial, the jury found for the defendants.[140] On appeal, the plaintiff argued that the district court erred in admitting the defendant's expert testimony that there was an "association" between Mr. Tompkin's asbestos exposure and an elevated risk of lung cancer.[141] The defendant's expert:

> [T]estified about the epidemiological association between lung cancer and Mr. Tompkin's asbestos exposure and smoking. Using data collected by the American Cancer Society, he compared the incidence of lung cancer in a "cohort" of individuals with smoking histories similar to Mr. Tompkin to the incidence of lung cancer in a "cohort" of individuals with no history of smoking. Using this same data, he also compared the incidence of lung cancer in a "cohort" of individuals with smoking histories and asbestos exposure similar to Mr. Tompkin with a "cohort" of individuals with similar asbestos exposure but who never smoked. Finally, using the same data, he compared the incidence of lung cancer in a "cohort" of individuals with smoking histories and asbestos exposure similar to Mr. Tompkin with the incidence of lung cancer in a "cohort" of individuals with no asbestos exposure.[142]

The defendant's expert in *Tompkin* concluded the plaintiff's lung cancer was not associated with smoking but with asbestos.[143] Here, epidemiological evidence was used to weaken the plaintiff's proximate

135. *See* Pub.L. No. 89-92, 79 Stat. 283, § 4 (codified as amended at 15 U.S.C. §§ 1331-1340 (2009)).

136. *See, e.g.*, Boerner v. Brown & Williamson Tobacco Co., 394 F.3d 594, 600 (8th Cir. 2005) (noting Federal Cigarette Labeling and Advertising Act did not preempt design defect claim); Engle v. Liggett Group, Inc., 945 So. 2d 1246, 1276 (Fla. 2006) (overturning a $145 billion verdict against a cigarette company).

137. 362 F.3d 882 (6th Cir. 2004).

138. *Id.* at 885.

139. *Id.*

140. *Id.* at 886.

141. *Id.*

142. *Id.* at 889.

143. *Tompkin*, 362 F.3d at 889.

cause argument.

On the other hand, in *United States v. Phillip Morris USA, Inc.*, epidemiological evidence was used to bolster the plaintiff's case.[144] In that case, the government relied on several studies showing the link between cigarette smoking and lung cancer, to make the argument that Phillip Morris violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961–1968.[145] The government alleged that Phillip Morris engaged in a lengthy, unlawful conspiracy to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the health benefits from low tar, "light" cigarettes, and their manipulation of the design and composition of cigarettes in order to sustain nicotine addiction.[146] The district judge found that there was overwhelming evidence to support most of the Government's allegations.[147]

It is, however, instructive to note here that in tobacco cases, disclosure that tobacco companies had for a long time known about the harmful effects of smoking but failed to disclose the facts, helped plaintiffs in their litigation.[148] This is unlike other public health litigation where the issue of disclosure is not usually a primary point of contention.

Another group of cases that relied heavily on epidemiological evidence were the Bendectin cases including *Brock v. Merrell Dow Pharmaceuticals Inc.*,[149] *Ealy v Richardson-Merrell Inc.*,[150] and *Daubert v. Merrell Dow Pharmaceuticals Inc.*[151] In *Brock*, plaintiffs brought suit claiming injury from ingesting a drug manufactured by defendant, Merrell

144. 449 F. Supp. 2d 1 (D.C. Cir. 2006).

145. *Id.* at 26–28.

146. *Id.*

147. *Id.* at 27.

148. *See generally* Boerner v. Brown & Williamson Tobacco Co., 394 F.3d 594 (8th Cir. 2005). Although punitive damages were conditionally remitted from fifteen million to five million dollars, the Court of Appeals held that there was ample evidence to support a finding that the tobacco company was aware cigarettes contained carcinogens and nicotine. *See id.* at 601–03. Also, there was sufficient evidence that the tobacco company was aware as early as the 1950s and 1960s that the risk of cancer increased with the amount of exposure. *See id.* at 601; *see also* Burton v. R.J. Reynolds Tobacco Co., 208 F. Supp. 2d 1187 (D. Kan. 2002) (holding that whether the tobacco company failed to warn the public of the dangers of smoking before the 1969 regulation took effect was a question for the jury); Bullock v. Phillip Morris USA, Inc., 159 Cal. App. 4th 655 (Cal. 2d Dist. Ct. App. 2008) (although twenty eight million dollar punitive damage award was reversed, liability for fraudulent concealment and failure to warn of a design defect was limited to acts and omissions prior to enactment of Federal Cigarette Labeling and Advertising Act).

149. 874 F.2d 307 (5th Cir. 1989).

150. 897 F.2d 1159 (D.C. Cir. 1990).

151. 509 U.S. 579 (1993).

Dow Pharmaceuticals.[152] Regarding the sufficiency of the evidence presented, the *Brock* Court wrote:

> Undoubtedly the most useful and conclusive type of evidence in a case such as this is epidemiological studies. Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it — in this case ingestion of Bendectin during pregnancy. To define that relationship, the epidemiologist examines the general population, comparing the incidence of the disease among those people exposed to the factor in question to those not exposed. The epidemiologist then uses statistical methods and reasoning to allow her to draw a biological inference between the factor being studied and the disease etiology.[153]

In *Ealy v. Richardson-Merrell, Inc.*, defendant, Merrell Dow, appealed a jury award of compensatory damages to plaintiff Ealy, due to injury resulting from plaintiff's use of defendant's product, Bendectin.[154] In reversing the lower court, the appellate court reasoned that the then existing body of published epidemiological studies had found no significant statistical association between the ingestion of Bendectin and birth defects.[155] On the other hand, in *Daubert*, the United States Supreme Court established the general applicable standard for admission of expert testimony.[156] In *Daubert*, petitioners' parents alleged that the mothers' ingestion of Bendectin resulted in the children having birth defects.[157] The district court granted summary judgment to respondent on the ground that published scientific evidence did not show a statistical link between use of Bendectin and birth defects.[158] The appellate court affirmed, but the Supreme Court reversed holding that general acceptance is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence.[159]

There are other cases where epidemiology may have played a role in either supporting or weakening the strength of the evidence, though the cases did not involve public health litigation. One notable case is *District of Columbia v. Heller*.[160] In *Heller*, the United States Supreme Court held that the Second Amendment conferred an individual right to keep and bear

152. *Brock*, 874 F.2d at 308.
153. *Id.* at 311.
154. *Ealy*, 897 F.2d at 1159.
155. *Id.* at 1164.
156. *Daubert*, 509 U.S. at 597.
157. *Id.* at 582.
158. *Id.* at 583–584.
159. *Id.* at 597–598.
160. 128 S. Ct. 2783 (2008).

arms.[161] Justices Breyer, Stevens, Souter, and Ginsburg in their dissent cited several studies showing that handguns are involved in a majority of firearm deaths and injuries in the United States.[162] Studies suggested for example, that urban areas have different experiences with gun related death, injury and crime than less densely populated areas.[163] Although the case was decided on different grounds, the role of public health studies (read epidemiology) linking firearms deaths and injuries was given credence by the dissent.[164] Commenting on this decision, Doctors Drazen, Morrissey and Curfman, in an editorial in the New England Journal of Medicine, note that overturning of a handgun ban in Washington DC has launched the country on a risky epidemiologic experiment.[165] Collectively they write that:

> With the Supreme Court's decision and the expectation of a substantial reduction in gun regulation, we are poised to witness another epidemiologic study of the effect of regulation on gun violence. With this experiment, which may play out in many American cities, we will know in the coming years whether the overturned laws reduced death and injury from handguns. The Court has heard the arguments and made its decision; we will now learn the human ramifications of this landmark case.[166]

*District of Columbia v. Heller* was a Second Amendment case.[167] Naturally, the issue of epidemiologic causation was not germane. A notable theme in these cases is that some courts allow the use of epidemiological evidence without direct causation. I think this is a good trend because requiring direct causation in all cases where there is general consensus in causation would be restrictive and scientifically inadequate. For example, while epidemiology is recognized as a powerful and useful tool in assessing etiologic relations, many causal associations have been established in the absence of epidemiologic proof. In some of these cases, the outcome might be considered a signature of the exposure and pathologic studies, thus, case reports and animal studies would be sufficient to convince the scientists that a causal relation exists.[168] To insist on direct causation every time, therefore, would be to go against the weight of

161. *Id.* at 2791.

162. *Id.* at 2854–55.

163. *See id.* at 2857.

164. *See id.* at 2860–61.

165. *See* J. M. Drazen, S. Morrissey & G. D. Curfman, *Guns and Health*, 359 NEW ENG. J. MED 517, 517–18 (2008).

166. *Id.*

167. 128 S. Ct. 2783, 2787–88 (2008).

168. *See, e.g.*, Arthur Bryant & Alexander Reinert, *Epidemiology in the Legal Arena and Search for Truth*, 154 AM. J. EPIDEMIOLOGY S29 (Supp. 2001).

science.

Other Courts, however, recognize the important role epidemiological evidence may play in demonstrating causation of illness or disease and have held that in the absence of either epidemiological evidence or scientific understanding of causation, a finding of causation must be rejected as speculative.[169] Causation is in turn classified by the courts as general and specific as discussed below.

## III. GENERAL V. SPECIFIC CAUSATION

The two legal concepts of causation discussed by most of the courts cited above are general causation and specific causation. As Patricia Lin stated:

> Traditionally, courts have admitted few kinds of scientific evidence to prove causation, usually allowing only two forms: epidemiological evidence to prove general causation and specific causation where the studies showed that exposure causes risk levels to double,[170] and medical testimony by the plaintiff's personal physicians.[171]

Moreover, in differentiating between general and specific causation, it has been noted that:

> Courts define general causation as "the capacity of a product to cause injury,"[172] and specific causation as "proof that the product in question caused the injury of which the plaintiff complains."[173] General causation may be thought of as a scientifically established cause-and-effect relationship. To satisfy this burden, sufficient hypotheses and testing must be demonstrated to establish that a disease or condition can arise from exposure to a certain substance. Specific causation, on the other hand, involves a variety of factors including level, duration and proximity of exposure, also known as "dose," which tend to show that the person's alleged exposure, in fact, caused his or her condition.[174]

169. *See* 63 AM. JUR. 2D *Products Liability* § 66 (2008).

170. Patricia Lin, *Opening the Gates to Scientific Evidence in Toxic Exposure: Medical Monitoring and Daubert*, 17 REV. LITIG. 551, 575 (1998).

171. *Id.*

172. William Dillingham et al., *Blueprint for General Causation Analysis in Toxic Tort Litigation*, FDCC Q., Fall 2003, *available at* http://findarticles.com/p/articles/mi_qa4023/is_200310/ai_n9344352/print?tag=artBody;col1; *see also* Siharath v. Sandoz Pharm. Corp., 131 F. Supp. 2d 1347, 1352 (N.D. Ga. 2001) (noting that general causation is the capacity of a product to cause injury; specific causation is proof that the product in question caused the injury of which the plaintiff complains).

173. Dillingham et al., *supra* note 172.

174. *Id.*

Although both judges and juries evaluate epidemiologic evidence, judges must initially decide whether the testimony is admissible.[175] For example, in *Norris v. Baxter Healthcare Corp.*,[176] the Tenth Circuit Court of Appeals held that certain proposed expert testimony was unreliable as to both general and specific causation, and thus inadmissible.[177] The plaintiff's underlying complaint was a products liability action against an implant manufacturer, and the plaintiff claimed systemic autoimmune disease and local injuries from a silicone breast implant.[178] The United States District Court for the District of Colorado had granted summary judgment in favor of defendant, the successor of the breast implant manufacturer, and as such, plaintiff sought review of the decision.[179] The appellate court affirmed the district court's finding that plaintiff's experts did not offer valid testimony to support either general or specific causation.[180] The plaintiff's experts completely ignored or discounted without explanation the many epidemiological studies which found no medically reliable link between silicone breast implants and systemic disease.[181] The *Norris* Court reasoned that epidemiology is the best evidence of general causation in a toxic tort case.[182]

Similarly, in *Young v. Burton*,[183] plaintiffs sued an attorney and his law firm for legal malpractice based on their failure to file a timely personal injury lawsuit.[184] Plaintiffs' expert, Dr. Shoemaker, used his own differential diagnostic procedure for mold illness which involved a two-tiered analysis.[185] The expert stated that to satisfy the first tier, there must be: (1) the potential for exposure; (2) the presence of a distinctive group of symptoms; and (3) the absence of confounding diagnoses and exposures.[186] The second tier looked at levels of certain hormones and enzymes in the blood which are altered by exposure to a biotoxin and thus served as biomarkers.[187] Defendants moved to exclude the expert's testimony arguing that there was no evidence as to the exact substance plaintiffs were exposed to or the level at which they were exposed, and thus formal

175. *See* Bryant & Reinert, *supra* note 168, at S27.
176. 397 F.3d 878 (10th Cir. 2005).
177. *Id.* at 879, 881, 885–87.
178. *Id.*
179. *Id.* at 879–80
180. *Id.* at 882–83, 886–88.
181. *Id.* at 884–85.
182. *See Norris*, 397 F.3d at 882.
183. 567 F. Supp. 2d 121 (D.C. Cir. 2008).
184. *Id.* at 122.
185. *Id.* at 124.
186. *Id.*
187. *Id.*

toxicological causation analysis could not be performed.[188]

In finding for the defendant, the court in *Young* held that plaintiffs' expert's diagnosis and opinions as to general and specific causation of injuries allegedly caused by their exposure to mold were not sufficiently grounded in scientifically valid principles and methods to satisfy *Daubert*.[189] The original lawsuit would have sought recovery for damages suffered by plaintiffs as a result of exposure to toxic mold while residing at an apartment complex. In discussing causation, the court stated that in a toxic tort case, "[t]he plaintiff must show that the toxicant in question is capable of causing the injury complained of (general causation) and must further prove that the toxicant in fact did cause that injury in the present case (specific causation)."[190] Here, both general and specific causation were lacking. The problem with this jurisprudence is that the litigant needs to prove both general and specific causation in order to prevail. As discussed in Part II.B, this is a standard that is not always consistent with the scientific principles.[191]

The same governing legal standards used in the above cases also apply to public health litigation. An underlying theme in most of these cases is that unlike general causation, specific causation is difficult to prove with epidemiological evidence. Epidemiology deals with populations not with individuals. It is, therefore, doubly difficult to win a mass torts case based on specific causation as illustrated by the Merck strategy below.

In the recent Vioxx cases, Merck Pharmaceutical focused on individuals.[192] This was thought to be a brilliant strategy, principally because of the difficulty in establishing specific causation by the plaintiffs. Merck was able to win most of the individual cases that went to trial.[193] For example, in *Merck & Co., v. Ernst*,[194] "[Merck appealed] from a jury verdict in a personal-injury and wrongful-death suit filed by Carol Ernst in which she alleged that ingestion of Vioxx caused the sudden cardiac death of her husband . . . ."[195] Merck challenged "the legal and factual

188. *Id.* at 122, 126.

189. *See Young*, 567 F. Supp. 2d at 122 (applying Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), a decision that addresses the rules of expert testimony).

190. *See id.* at 138.

191. *See supra* Part II.B.

192. *See* Alex Berenson, *Plaintiffs Find Payday Elusive in Vioxx Suits*, N.Y. TIMES, Aug. 21, 2007, at A1.

193. *See* Howard M. Erichson, *Mass Torts Litigation Blog: The Vioxx Settlement*, http://lawprofessors.typepad.com/mass_tort_litigation/2007/11/the-vioxx-settl.html (last visited July 06, 2010).

194. 296 S.W.3d 81 (Tex. Ct. App. 2009).

195. *Id.* at 83.

sufficiency of the evidence to support the jury's verdict on causation . . . .[196] At trial, Ernst alleged that her husband's "death was caused by a blood clot triggered by [ingestion of] Vioxx.[197] The blood clot, however, was not found by the autopsy.[198] "Merck argued that [Ernst] failed to present competent evidence of the existence of such a clot."[199] The court stated that "the epidemiological evidence [supported] the conclusion that Vioxx use[d] at a certain dose and duration is associated with an increased risk of thrombotic cardiovascular events."[200] However, because there was no direct evidence of a blood clot, Ernst failed to prove specific causation.[201] It is instructive to point out here, that in the trial, the jury had awarded Carol Ernst a total of $24,450,000 in compensatory damages and assessed $229,000,000 in exemplary damages, later reduced to a sum of $26,100,000 by the trial judge.[202]

Here again is another example where the epidemiological evidence was weak to prove specific causation, but the jury disregarded the science and found for the plaintiff. This was a glaring anomaly. Trial strategy aside, perhaps the question here is whether epidemiologic evidence is so complex that sometimes it confuses the jury. Maybe the goal should be to explain to the jury the differences between specific and general causation or at least elucidate the relevance of epidemiological evidentiary standard to them.

Generally, specific causation demands that the connection between the exposure and the specific injuries or illness alleged should not be subject to reasonable dispute.[203] In a toxic tort case involving mold for example, "specific causation would require the identification of type of mold alleged to result in injuries, specifics relating to exposure, proximity, duration and alleged exposure pathway and medical issues, such as the onset or absence of symptoms relative to the specific exposure . . . ."[204] This is a much higher standard than for general causation. It is no wonder then, that Merck has been able to prevail in most of its Vioxx cases.[205]

196. *Id.*
197. *Id.* at 90.
198. *Id.*
199. *Id.*
200. *Ernst*, 296 S.W.3d at 99.
201. *See id.* at 99–100.
202. *See id.* at 90.
203. *See generally id.* at 95–98.
204. Stephen J. Henning & Daniel A. Berman, *Mold Contamination: Liability and Coverage Issues: Essential Information You Need to Know For Successful Handling and Resolving Any Claim Involving Toxic Mold*, 8 HASTINGS W.N.W. J. ENVTL. L. & POL'Y 73, 91 (2001).
205. *See* Alex Berenson, *Plaintiffs Find Payday Elusive in Vioxx Suits*, N.Y. TIMES, Aug 21,

## IV. TENSIONS RAISED BY THE EPIDEMIOLOGICAL EVIDENTIARY STANDARD

The epidemiological evidentiary requirement ("a showing that a population of individuals exposed to the substance faced at least twice the risk of suffering the injury in question") has been widely criticized for being inconsistent with tort principles.[206] "To bolster the case against the epidemiological evidentiary requirement, critics argue that the requirement inappropriately relies on scientific norms rather than tort norms."[207] However, "[s]cientific norms do undoubtedly differ from tort norms."[208]

First, epidemiology is a science that relies on statistical significance. This can sometimes be fraught with uncertainties. An epidemiologic investigation begins with the "null hypothesis," the hypothesis that the agent studied has no effect in causing the disease. "Disproving the null hypothesis does not prove conclusively that such a causal role exists, for it may be sheer coincidence or methodologic errors that result in the observation."[209]

Second, epidemiologic studies are susceptible to a variety of errors-termed "biases" by scientists-that may affect the validity of the studies' results.[210] These biases include selection bias which "occurs when the exposed group is selected in a way that makes it more or less susceptible to disease for reasons independent of exposure."[211] "Diagnostic bias or ascertainment error occurs when the disease in question is not accurately determined."[212]

Critics have noted that "the most obvious problem with the evidentiary requirement is that it provides inadequate incentives for manufacturers to fund epidemiological study."[213] "As between individual plaintiffs and manufacturers, the cost of epidemiological study is most easily borne by manufacturers."[214] Manufacturers do not have an adequate incentive to incur the cost of epidemiological or other study so if plaintiffs

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2007, at A1.

206. Geistfeld, *supra* note 48.

207. *Id.* at 1016.

208. *Id.*

209. Michael D. Green, *Legal Theory: Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 646 (1992).

210. *Id.* at 649.

211. *Id.*

212. *Id.*

213. Geistfeld, *supra* note 48, at 1015.

214. *Id.*

bear the burden of producing such evidence, manufacturers typically choose ignorance.[215] Finally, "critics point to the unfairness of placing the entire burden of uncertainty on plaintiffs, the outcome produced by the epidemiological evidentiary requirement."[216]

These critics are misguided in the following areas. First, courts have consistently held that epidemiological and biological evidence are key components to all well-recognized scientific frameworks that examine causation of human diseases.[217] These frameworks include the IOM and Bradford- Hill criteria discussed in Part II.A.[218] Second, "an increasing number of courts have also held that causation must be established by epidemiological evidence showing that a population of individuals exposed to the substance faced at least twice the risk of suffering the injury."[219] According to this standard, "an epidemiological study that shows a doubling of risk (a relative risk of 2.0 in statistical terms) means that it is 50% likely that any particular case of the disease is attributable to the exposure rather than unexplained causes, or 'background risk.'"[220] Third, the ordinary evidentiary standard, based on preponderance of the evidence is more than adequate in allocating the burden of uncertainty. "The mere fact that one party bears the entire burden of uncertainty under an evidentiary rule, such as the one requiring epidemiological proof, does not necessarily violate a tort norm of equality."[221] These tensions though have important policy implications.

## V. POLICY IMPLICATIONS OF EPIDEMIOLOGICAL EVIDENCE

There are two major areas of policy that implicate epidemiological evidence. First, what weight should be given to epidemiological evidence and second, should epidemiologists even get involved in litigation and policy? Epidemiological evidence is essential for interpreting a body of scientific information, particularly when studies indicating different findings have been presented that lack consistency.[222] Courts must then

215. *See id.*

216. *Id.* at 1016–17.

217. *See, e.g.*, Gannon v. United States, 571 F. Supp. 2d 615, 641 (E.D. Pa. 2007); Lima v. United States, 508 F. Supp. 897, 907 (D. Colo. 1981), *aff'd*, 708 F.2d 502 (10th Cir. 1983); Berry v. CSX Transp., Inc., 709 So. 2d 552, 558 (Fla. 1st Dist. Ct. App. 1998).

218. *See* discussion *supra* Part II.A.

219. Geistfeld, *supra* note 48, at 1012–13.

220. Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 349–50 (1999).

221. Geistfeld, *supra* note 48, at 1017.

222. *See Gannon*, 571 F. Supp. 2d at 628–29.

decide whether to consider the studies presented or whether to ignore them. "Some courts have allowed a plaintiff's case to proceed to the jury without epidemiological data."[223]

As one example, in *Wells v. Ortho Pharmaceutical Corp.*, the Eleventh Circuit Court of Appeals held that "a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists."[224] The *Wells* Court additionally stated that:

> As long as the basic methodology employed to reach such a conclusion is sound, . . . products liability law does not preclude recovery until a 'statistically significant' number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical.[225]

In *Wells*, an infant and her parents brought suit against a manufacturer of a spermicide which allegedly caused the infant plaintiff to be born with birth defects.[226] The district court awarded $5.1 million to the plaintiffs, and the manufacturer appealed.[227] The Court of Appeals found that the plaintiffs had proven to a reasonable degree of medical certainty that the manufacturer's spermicide caused the infant's birth defects even though the district court had found the studies inconclusive on the ultimate issue of whether the product caused the plaintiffs' birth defects.[228] Here, the Court thought it prudent not to wait until a number of people were injured before imposing liability on the manufacturer.[229] The *Wells* Court placed more emphasis on the methodology than the results.[230]

This approach seems to be in tandem with the U.S. Supreme Court's holding in *General Electric Co. v. Joiner*,[231] discussed in the introduction. In *Joiner*, Justice Breyer, in a concurring opinion, noted that in exercising their gatekeeper role, judges must:

> [M]ake subtle and sophisticated determinations about scientific methodology and its relation to the conclusions an expert witness seeks to offer, particularly when a case arises in an area where the science

223. DAVID FAIGMAN ET AL., SCIENCE IN THE LAW: STANDARDS, STATISTICS AND RESEARCH ISSUES, 287 (West Group 2002).

224. 788 F.2d 741, 745 (11th Cir. 1986) (quoting Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1535 (D.C. Cir. 1984)).

225. *Id.* at 745 (quoting *Ferebee*, 736 F.2d at 1535–36).

226. *Id.* at 742.

227. *Id.*

228. *See id.* at 744-45.

229. *Id.* at 745.

230. *See Wells*, 788 F.2d at 745.

231. 522 U.S. 136 (1997).

> itself is tentative or uncertain, or where testimony about general risk levels in human beings or animals is offered to prove individual causation.[232]

However, Justice Breyer added that "judges are not scientists and do not have the scientific training that can facilitate the making of such decisions."[233]

Another factor impacting the weighting of studies is the study design. Where a party presents epidemiological evidence, study designs may still be different. This may require different weighting. "In most product liability cases for example, three types of expert scientific evidence are presented: experimental, clinical and epidemiologic."[234] Courts tend to give more weight to human studies because they tend to directly link exposure to injury as opposed to laboratory experiments.[235] "Experimental research, conducted by toxicologists, pharmacologists and tumor biologists is weighted more heavily when there are modest or no human research results or when the epidemiology study results are equivocal."[236] It behooves attorneys, therefore, to focus more on human studies.

While human studies are the gold standard of showing a correlation between the exposure and the disease, it is axiomatic that one cannot freely experiment on human beings; therefore, the emphasis on human studies may also be misplaced. Furthermore, most epidemiological work is observational not experimental, so putting more emphasis on experimental research does not necessarily indicate that the best evidence is admitted.[237]

The second policy question is whether epidemiologists should get involved in litigation and policy issues. Perhaps this is a problem that affects the wider scientific community in general. The American College of Epidemiology guidelines state that the primary role of epidemiology is "the design and conduct of scientific research and the public health application of scientific knowledge."[238] One group of commentators has

232. *Id.* (Breyer, J., concurring).

233. *Id.* at 148.

234. GOLDSMITH & ROSE, *supra* note 133, at 69.

235. *See generally* Allen v. Penn. Engr. Corp., 102 F.3d 194, 197 (5th Cir. 1996) (noting that appellants' reliance on animal studies furnishes at best speculative support for their causation theory).

236. GOLDSMITH & ROSE, *supra* note 133, at 69.

237. *See* Bryant & Reinert, *supra* note 168 at S30 (noting that "All areas of scientific discipline may be relevant to etiologic conclusions: clinical observations, animal studies, toxicologic studies, and chemical analysis. In some cases, epidemiology is the most useful tool for evaluating cause-effect relations, but not in every case").

238. AMERICAN COLLEGE OF EPIDEMIOLOGY. ETHICS GUIDELINES. ANN. EPIDEMIOL. 10, 487–97 (2000).

opined that many epidemiologists lack policy expertise.[239] The group contends that science is an attempt to achieve a deeper level of understanding, not an attempt to establish public policies.[240] The job of scientists, according to this school of thought, "should be to formulate and evaluate scientific hypotheses, rather than to muster support for or marshal evidence against specific policies."[241]

Stripped to its essentials, this group argues for keeping epidemiology out of the courtroom because there may be a danger in epidemiologists conducting research in anticipation of litigation, therefore, diluting their hypothesis. But this argument is as seismic as it is unconvincing. First, there has been a steady rise of epidemiology in the courtroom.[242] Second, epidemiologists practice in many forms of legal and policy making areas: and third, participation of scientists in the court room is not an issue exclusive to epidemiologists alone. To argue otherwise would be to bar all scientists from the courtroom.

## VI. CONCLUSION

This paper has discussed the role of epidemiology in mass torts and public health litigation by analyzing some of the recent cases where epidemiological evidence was debated and how the evidence is affecting the policy of mass torts and public health litigation. There is no doubt that the use of epidemiological evidence is helpful to the fact finder. The problem is what standard courts should use to admit the evidence.

I argue for a heightened standard of admission. What this means is that judges should be given latitude to scrutinize and screen more carefully epidemiological studies especially where the science itself is tentative or uncertain. This heightened standard is a screening standard for admission that considers not only a doubling of the risk by the exposure, (the epidemiological Gold standard is relative risk of 2.0) but also jury instructions that clearly inform the jury of the strengths and weaknesses of epidemiological studies. In turn, the scientific community should provide feedback to the legal community and judges in particular about whether

239. *See* Kenneth J. Rothman & Charles Poole, Letter to the Editors, *Epidemiologic Science and Public Health Policy*, 43 J. CLIN EPIDEMIOL 1270 (1990); *see also* Savitz et al., *Reassessing the Role of Epidemiology in Public Health*. 89 AM. J. PUB. HEALTH 1158, 1158–1161 (1999).

240. *See* Savitz et al., *supra* note 239, at 1158–1161.

241. Kenneth J. Rothman & Charles Poole, *Science and Policy Making Letter*, 75 AM. J. PUB. HEALTH 340, 341 (1985).

242. See *infra* Parts II.A–B for a discussion on vaccine related cases and non-vaccine related cases.

science is being used correctly.[243]

Additionally, the American College of Epidemiology and the CSTE should develop model guidelines for the use of epidemiological evidence in the courtroom. These guidelines could mirror the public health law bench books that have been developed for some states to deal with public health emergencies.[244] The Bench Books are "intended to protect the health and safety of communities by improving legal preparedness for both public health emergencies and more routine public health cases."[245] They are reference tools "that judges may use as they confront the range of public health issues that come to their courtrooms."[246] To be sure, there will always be tensions raised by the epidemiological evidence, because scientific standards and legal standards are not likely to be in perfect harmony. However, model epidemiological evidence guidelines, ala public health bench books discussed above, would help insure some kind of uniformity in the use of epidemiological evidence in courtrooms throughout the nation.

243. *See* Bryant & Reinert, *supra* note 168.

244. *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, *Portfolio of Public Health Law Benchbooks and Other Judicial Resources*, http://www2a.cdc.gov/phlp/lawmat.asp (last visited July 7, 2010).

245. *Public Health Law Bench Book For Indiana Courts*, Center for Public Health Law Partnerships, University of Louisville, *available at* http://www.ojp.usdoj.gov/BJA/pandemic/INBenchBook.pdf (last visited July 7, 2010).

246. *Id.*