THE SECRET LIFE OF (MASS) TORTS: THE 'BENDECTIN LITIGATION' AND THE CONSTRUCTION OF LAW-SCIENCE KNOWLEDGES

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I. INTRODUCTION

The United States litigation surrounding birth defects allegedly caused by the morning sickness drug Bendectin has received considerable attention in legal literature. The Bendectin litigation is often used as an exemplary case of the promotion by the legal system of 'unreliable' science. In this framework, the Bendectin litigation has been interpreted as a form of illegitimate de facto regulation of the manufacture of pharmaceuticals and a massive waste of scientific, financial and judicial resources. In such accounts there has also been considerable discussion of the weight courts should assign to various types of scientific knowledge involved in establishing causality in relation to birth defects. For instance, the relative status which should be afforded to *in vitro, in vivo*, chemical structure analysis, epidemiology, and epidemiological re-analysis has been the subject of intense debate. Scientific studies have also been differentiated and ranked according to whether or not they were published and peer reviewed, replicated, or whether they were produced for use in litigation. Most accounts of the Bendectin litigation have portrayed a situation where courts, in spite of extraneous pressures to 'distort' adequate scientific judgments, have managed to resolve the matter by recognising the 'self-evident' scientific primacy of published epidemiological studies. Such studies, it is argued, suggest that Bendectin is not harmful. There has also been a tendency in these accounts to explain the existence of the Bendectin controversy merely as a by-product of opportunistic lawyers and scientific fraud. In the following article we will argue that these accounts are far too simplistic. In undertaking a more detailed empirical examination of the history of the Bendectin litigation it can be shown that there was no simple mechanism by which published epidemiology came,

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eventually, to be seen as the primary means for determining causation. In many accounts this process is represented as inevitable; simply an instance of 'rationality' prevailing. However, such accounts leave the so-called 'distorting' factors responsible for perpetuating the litigation - usually attributed to unscrupulous lawyers and scientists - philosophically and empirically underdeveloped. They fail to explain why such an apparently 'obvious' epidemiological resolution was not universally accepted by courts from the outset. There is a tendency in these accounts to engage in what is sometimes described as a sociology of error.[1] In our account we will argue that such influences should not be explained away as errors. Rather, the primacy of epidemiology is seen to be the outcome of complex social negotiations transpiring over time. It can be argued that the decision, by courts, to privilege published epidemiological studies is amenable to political analysis. Individual courts constructed the meaning of the specific evidence at hand, taking into account broader factors including past legal proceedings (such as the Agent Orange litigation and earlier Bendectin cases), anticipation of future policy and jurisprudential implications (such as the so-called 'litigation explosion' and 'insurance crisis') and concerns about the efficient use of 'scarce' judicial resources.[2] In providing a more detailed examination of the Bendectin litigation, a number of questions are raised about the mutual constitution - by law and science - of knowledge in legal contexts. Recognition of the important sense in which there is a 'mutual constitution' of law-science knowledges has a number of implications for the understanding of scientific controversies in mass torts.

Before embarking on an examination of some of the existing accounts of the Bendectin litigation we provide a brief overview of the history of this litigation which we believe would be acceptable, even to those commentators with whom we disagree. The differences will emerge later.

II. HISTORY OF BENDECTIN

Bendectin, marketed as Debendox in Australia and the United Kingdom, was a prescription anti-nausea drug used by millions of pregnant women from 1956-1983, before it was removed from the market, purportedly due to the impact of

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1 M Mulkay, *Science and the Sociology of Knowledge*, Allen & Unwin (1979), B Barnes, *Scientific Knowledge and Sociological Theory*, Routledge (1974) pp 130-51

2 M Galanter, "Reading the Landscape of Disputes What We Know and Don't Know (and Think We Know) About Our Allegedly Contentious and Litigious Society" (1983) 31 *UCLA Law Review* 4, M Galanter, "The Day After the Litigation Explosion" (1986) 46 *Maryland Law Review* 3, M Saks, "If There Be a Crisis, How Shall We Know It?" (1986) 46 *Maryland Law Review* 63; M Saks, "Do We Really Know Anything about the Behavior of the Tort Litigation System - And Why Not?" (1992) 140 *University of Pennsylvania Law Review* 147, JA Henderson and T Eisenberg, "The Quiet Revolution in Products Liability: An Empirical Study of Legal Change" (1990) 37 *UCLA Law Review* 479; T Eisenberg and JA Henderson, "Inside the Quiet Revolution in Products Liability" (1992) 39 *UCLA Law Review* 731; J Siliciano, "Mass Torts and the Rhetoric of Crisis" (1995) 80 *Cornell Law Review* 990; AI Youmans, "Research Guide to the Litigation Explosion" (1987) 79 *Law Library Journal* 707

litigation on the pharmaceutical manufacturer, Merrell.[3] After a decade of public 'concern' and a few 'ambiguous' epidemiological reports in the late 1970s, a growing number of children and their guardians sought damages from Merrell for injuries allegedly sustained through the mother's ingestion of the drug. To obtain damages, the standard of proof required in United States civil litigation is the civil burden: 'on the balance of probabilities' that Bendectin caused the specific damage. The type of case meant that plaintiffs were effectively required to prove causation with scientific evidence. Throughout the 1980s and continuing, though diminishing, into the 1990s, Bendectin litigation has been ongoing in the United States Federal and State courts.

There have been a number of accounts of the Bendectin litigation. The discussion in the following two sections will explore a representative sample of these accounts, all of which we will argue display a lack of sophistication in their understanding of law-science interactions. In section III we will begin by examining the accounts of Huber,[4] Black,[5] and Lasagna and Shulman,[6] which display the least sophistication. In Section IV we will consider the more sophisticated, though under-developed, accounts of Sanders[7] and Green.[8]

III. NAIVE ACCOUNTS OF THE 'BENDECTIN LITIGATION': HUBER, BLACK, LASAGNA AND SHULMAN

A feature common to the accounts of Black and Huber is to describe problems surrounding the Bendectin litigation as the result of knowledge claims produced by 'faulty' scientific reasoning being admitted to courts and then placed before credulous juries. Black and Huber are both reluctant to accept that the jury should be placed in the position of evaluating between the claims of experts. They argue that the Bendectin litigation did not represent a legitimate 'battle of the experts' because those insisting that Bendectin is harmful were not basing their arguments on scientific reasoning. The implication is that the courts should never have allowed such claims to have been admitted for evaluation by a jury. It is ironic that neither Huber nor Black engage in a detailed scientific evaluation of the reasoning used by the defenders or detractors of Bendectin. Rather, the evidence raised to discredit the apparent dangers of Bendectin involves claims about the motivations and ethics of various scientists (plaintiff scientists). In

3 The company manufacturing Bendectin has changed over the years but 'Merrell' has always remained in the name. The pharmaceutical manufacturer will hereafter be called 'Merrell'.

4 P Huber, *Galileo's Revenge Junk Science in the Courtroom*, Basic Books (1991).

5 B Black, "A Unified Theory of Scientific Evidence" (1988) 56 *Fordham Law Review* 595

6 L Lasagna and SR Shulman, "Bendectin and the Language of Causation" in K Foster, D Bernstein, P Huber (eds), *Phantom Risk. Scientific Inference and the Law*, MIT Press (1993) p 101.

7 J Sanders, "The Bendectin Litigation A Case Study in Life Cycles of Mass Torts" (1992) 43 *Hastings Law Journal* 301

8 MD Green, "Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation The Legacy of Agent Orange and Bendectin Litigation" (1992) 86 *Northwestern University Law Review* 643.

particular much is made of the demise of McBride for scientific fraud and the issue of Done's credibility.[9]

Black's account is linked back to a number of earlier cases such as the *Agent Orange* litigation,[10] *Wells v Ortho Pharmaceutical Corp*,[11] and *Ferebee v Chevron Chemical Co.*[12] His discussion of these cases does not examine the scientific 'reasoning' behind them in any detail. Fundamentally, Black's challenge to courts admitting so-called 'flawed' scientific claims, draws its authority from reconstructions which rely on the use of accounts of 'scientific consensus' achieved 'separate' from litigation. Black makes much, in the context of the *Wells* case, of an article in the *New England Journal of Medicine* and statements made by the United States Food and Drug Administration (FDA). Black assumes that such 'consensus statements' do not in themselves represent positions motivated by the existence of litigation and social pressures 'external' to science, and that the scientific reasoning behind such statements will be transparently obvious.[13]

Huber's account of the Bendectin litigation[14] is premised on the assumption that once proceedings began to develop momentum science was all but ignored:

> From here on, the science of Bendectin, already overshadowed by sympathetic claimants, flamboyant lawyers, breathless ex-strippers, receptive journalists, and the rest, would become almost completely irrelevant.[15]

In making this claim Huber represents and reinforces his call for the separation of litigation from the construction of scientific knowledge. He later emphasises this point when he cites the supposed scientific consensus over the lack of harmful effects of Bendectin drawn from scientific sources outside of litigation:[16] "no one can be quite sure what caused their [plaintiffs'] heart-wrenching injuries, but it clearly wasn't Bendectin".[17]

There is a very strong suggestion that the Bendectin litigation only existed as a by-product of 'corrupt' and 'greedy' plaintiff scientists and lawyers. This theme is reinforced throughout Huber's text. "Meanwhile, the prestigious magazine *Science* reported that McBride had been paid $5,000 a day to testify in

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9 For a polemical discussion of the 'evidence' provided by Dr William McBride and Dr Alan Done, see Huber, note 4 *supra*, pp 112-29. For a more detailed examination of McBride, see B Nicol, *McBride. Behind the Myth*, ABC Enterprises (1989) and McBride's response, *Killing the Messenger. An Autobiography*, Eldorado (1994). The credibility of Dr Alan Done, Professor of Paediatrics and Pharmacology, Medical Faculty of Wayne State University is discussed in some detail in *Oxendine v Merrell Dow Pharmaceuticals Inc* 563 A 2d 330 (DC App 1989).

10 *In re Agent Orange Product Liability Litigation* 597 F Supp 740 (DCNY 1984); *In re Agent Orange Product Liability Litigation* 611 F Supp 1221 (DCNY 1985); *In re Agent Orange Product Liability Litigation* 611 F Supp 1267 (DCNY 1985); *In re Agent Orange Product Liability Litigation* 818 F 2d 145 (2nd Cir 1987).

11 788 F 2d 741 (11th Cir 1986)

12 736 F 2d 1529 (DC Cir 1984)

13 Black, note 5 *supra*. Contrast S Jasanoff, *Science at the Bar Law, Science, and Technology in America*, Harvard University Press (1995) pp 44, 50-2, S Jasanoff, "What Judges Should Know About the Sociology of Science" (1992) 32 *Jurimetrics Journal* 345.

14 Huber , Ch 7, "Nausea The Massed Legal Attack", note 4 *supra*, p 117

15 Huber, note 4 *supra*, p 117.

16 *Ibid*, pp 126-7.

17 *Ibid*, p 128.

the Mekdeci trial".[18] And, "To the horror of the plaintiffs' lawyers, however, Judge Rubin resolved to run a trial not a casino."[19]

The contention that there may have been credible expert opinion that Bendectin was in fact a teratogen[20], or that the processes of litigation were inextricably linked to the study of Bendectin, find no expression.

These approaches are highly selective, in favour of the defendant, in a number of ways. First, claims appearing in litigation are undermined on the basis of their obvious 'partisanship' and by juxtaposing them, inaccurately, to claims developed away from litigation which are supposedly devoid of partisanship. Scientific evidence involved in litigation is rarely demarcated in these ways, and some authors have argued that partisanship is not unusual in the workings of science.[21] Secondly, Black and Huber's accounts are asymmetrical in that the motivations, allegiances, and interests of the Bendectin plaintiff scientists as well as their knowledge claims are subject to scrutiny but the defendant science is represented as impersonal and immune from scrutiny. In Huber's account this asymmetry is particularly obvious. For example, Huber attempts to discredit the value of a leading plaintiff expert, Done, implying that he has reworked epidemiology purely for the purposes of litigation to reveal a connection between Bendectin and birth defects. It is implied that Doctor Done's work can be compared to a more credible body of epidemiological data produced separately from the 'corrupting' influences of litigation. Huber's account glosses over the point that the existence of Bendectin litigation was an important stimulant, not only to Done's reworking of epidemiological studies, but the majority of epidemiological studies themselves.[22] Huber introduces a 1988 *Oxendine* appeal case,[23] where the judge was scathing in his evaluation of the conduct of Done. Huber recounts the judge's opinion as follows:

> Done's statements about his credentials, this judge declared, were "so deliberately false that all his testimony on behalf of [Oxendine] is suspect ... [Done's] lies went so much toward enhancing his status as a witness that he reeks of the hired gun who will say anything that money can buy as long as it is glibly consistent with prior testimony in other cases.[24]

Huber failed to acknowledge a subsequent appellate case which vindicated Done and reversed this assessment.[25]

Another account of the Bendectin litigation has been offered by Lasagna and Shulman. This account avoids the excessive asymmetries presented by Huber. Lasagna and Shulman provide very little direct criticism of the conduct of

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18 *Ibid*, p 116

19 *Ibid*, p 120.

20 Teratogen: Any factor or agent causing malformation in embryos.

21 R Albury, *The Politics of Objectivity*, Deakin University Press (1983), P Bourdieu, "The Specificity of the Scientific Field and the Social Conditions for the Progress of Reason" (1975) 14 *Social Science Information* 19; B Latour and S Woolgar, *Laboratory Life: The Social Construction of Scientific Facts*, Sage (1979).

22 Huber, note 4 *supra*, p 113. Compare Sanders, note 7 *supra*.

23 For a discussion of the reversal, see *Oxendine v Merrell Dow Pharmaceuticals Inc* 563 A 2d 330 (DC App 1989)

24 Huber, note 4 *supra*, p 123.

lawyers and scientists and the account does not focus on the science of McBride and Done, but displays some awareness of a broader base to the scientific studies deployed by parties involved in the actual Bendectin litigation. After an overview of the scientific studies, Lasagna and Shulman provide an analysis of the legal processes involved. At this point, their account converges with those of Black and Huber by reverting to an oversimplified reconstruction of how the issues were evaluated. In particular, Lasagna and Shulman introduce as unproblematic the primacy of epidemiology for legal decision-making: "[e]pidemiology supplies the best available evidence of the causal link, if any, between Bendectin and congenital anomalies."[26]

Lasagna and Shulman provide no clear reasons why epidemiology should be afforded such status. This point is surprising given that they raise the issue of the difficulties involved in establishing certainty and causation in epidemiology at another point in their discussion. In their conclusion, they offer a simplified reconstruction of the 'closure'[27] of the Bendectin 'problem': "In toxic tort cases, the courts have indicated that causation cannot be determined in the absence of epidemiological evidence."[28]

Curiously, this conclusion follows on from a brief discussion of the *Oxendine* case (discussed more fully below) in which an appellate court did not accept this very claim. In the face of this appellate decision, Lasagna and Shulman appear to blame jury incompetence for the outcome in *Oxendine* rather than challenge the 'naturalness' of the primacy they accord to epidemiology.

The accounts of Bendectin described above do not adequately explain the specific contingencies which were involved in constructing epidemiology as the primary form of scientific evidence.

IV. MORE REFINED INTERPRETATIONS: SANDERS AND GREEN

Both Sanders and Green endeavour to provide a more refined image of the complexities and processes involved in mass tort litigation. They provide a sense of shifting strategies and the influence of victories and losses on further litigation. They also place the Bendectin and Agent Orange litigation in a social context where judicial approaches are appropriated and redeployed. There is an emphasis on the importance of logistics and 'rationing' for the judges involved in administering trials as well as the acknowledgment that different scientific

25 *Oxendine v Merrell Dow Pharmaceuticals Inc*, 563 A 2d 330 (DC App 1989).

26 Lasagna and Shulman, note 6 *supra*, p 102.

27 For more complex accounts noting that the closure of scientific controversies involves the interplay of social-epistemological factors rather than a simple case of 'rationality' prevailing, see HM Collins, *Changing Order. Replication and Induction in Scientific Practice*, University of Chicago Press (1985); HM Collins and Trevor Pinch, *The golem: what everyone should know about science*, Cambridge University Press (1993) p 106.

28 Lasagna and Shulman, note 6 *supra*, p 116.

disciplines arrive at different 'conclusions' on specific issues.[29] On occasion they even suggest that law and science are engaged in a mutual process of knowledge production. However, despite their vast improvement on the polemics of Huber and selective historiography of Black, Lasagna and Shulman, both Sanders and Green, lacking tools to analyse the social construction of knowledge, ultimately revert to positivistic analyses.

Sanders begins his analysis by acknowledging that:

> [t]he history of the Bendectin litigation has been marked by questions concerning the relative probative value of each type of evidence and the causal inferences that can be drawn from statistical correlations.[30]

Already this is a substantial refinement on the analysis provided by other commentators. Sanders provides the reader with insights into the various types of evidence provided in Bendectin trials. He discusses the merits, costs and perceived advantages and disadvantages of different scientific techniques. Sanders even suggests some relationship between the availability of certain types of knowledge influencing the reception, interest and continued research undertaken in others.[31] Sanders accepts that litigation encourages scientific investigation which, in contradiction to Huber's discussion, is not a priori 'pathological'.

Unlike other more positivist accounts of Bendectin which tend to treat the scientific knowledge base in Bendectin litigation as something produced at a 'distance' from litigation, with litigation largely fulfilling the role of distorting scientific work, Sanders displays some awareness that the science involved in Bendectin shares a more complex interactive relationship with litigation: "There was a substantial mobilisation of resources devoted to the study of Bendectin, much of it apparently in response to litigation and concomitant political pressure."[32]

Sanders points out that there are a number of explanations for scientific mobilisation to study Bendectin in the wake of litigation, such as benefits to scientific careers, publication on a current topic and federal government grants. At one point, Sanders even goes as far as to suggest that legal needs "gave shape and direction to the epidemiological study of teratogenic effects".[33] The quantity of epidemiological research and its zenith in the 1980s corresponds with the peak of litigation and political pressure. This rise of epidemiological evidence and its value as a legal resource can also be argued to have exercised a negative effect on the quantity of *in vivo* studies which came to be seen as less valuable in legal contexts and thus fell behind in funding.

Sanders is at his most interesting when he discusses the complex interactions between law and science. He suggests:

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29 J Sanders, "From Science to Evidence: The Testimony on Causation in the Bendectin Cases" (1993) 46 *Stanford Law Review* 1 at 69, Green, note 8 *supra* at 676.

30 Sanders, note 7 *supra*, at 331

31 *Ibid* at 339, 345-6.

32 *Ibid* at 347.

33 *Ibid* at 346.

> We should anticipate that the science itself is influenced by the legal process. As the congregation of cases grows and matures, it creates its own gravity field, attracting and distorting the science that comes near it. In turn the science affects the law. Ultimately, science and law interact in complex ways to produce unique patterns of development in various case congregations.[34]

For Sanders, the areas where these interactions are most conspicuous are so-called 'trans-scientific' domains of uncertainty. That is, "uncertainty concerning an issue that can be put in scientific terms but for which scientific proof is unavailable".[35] Sanders provides an account which suggests that whilst initial scientific concern with Bendectin was promoted over time by legal pressures, scientific disagreement did not necessarily reflect adversely on the scientists involved. This was the case because the research questions involved in Bendectin did not neatly conform with pre-existing scientific research. The legal context, as a trans-scientific context of scientific uncertainty,[36] ultimately plays no role in distorting or constituting the ultimate content of scientific knowledge. Despite 'flagging' its potential importance, Sanders avoids developing a deeper systematic or detailed discussion of the interplay between the demands of litigation and the development of science. Rather than the context itself providing a 'site' in the ongoing constructions, translation and application of knowledges, it is merely a site of trans-scientific uncertainty.

Despite allusion to complex epistemological interactions between law and science and the recognition of the development of knowledges specifically for legal settings, Sanders falls prey to a creeping positivism:[37]

> Although there is considerable disagreement about the proper role of in vivo studies in answering that question many would agree they are less probative than epidemiological evidence.[38]

Yet the justification for the preference of the 'many' and the ability to make determinations between competing scientific knowledges is not justified epistemologically but socially. Having gone so far, Sanders seems unable to detect the extent of the epistemic struggle taking place within and around the Bendectin litigation. For Sanders, the inherent epistemological status of the epidemiological studies - rather than their interpretations, position in regulatory and legal culture and deployment by parties and judges - explains evidentiary developments. The inherent value of the studies and that recognition, and not the development of legal-scientific 'conventions', explains the shifts in judicial attitudes:[39]

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34 *Ibid* at 331

35 *Ibid* at 326

36 *Ibid* at 326; A Weinberg, "Science and Trans-Science" (1972) 10 *Minerva Law Review* 209, WE Wagner, "Trans-Science in Torts" (1986) 96 *Yale Law Journal* 428; WE Wagner, "The Science Charade in Toxic Risk Regulation" (1995) 95 *Columbia Law Review* 1613 Compare B Barnes and D Edge (eds), *Science in Context: Readings in the Sociology of Science*, MIT Press (1982) p 243, S Jasanoff, "Contested Boundaries in Policy Relevant Science" (1987) 17 *Social Studies of Science* 195.

37 Sanders, note 7 *supra* at 340· "whether the study has any objective indication that Bendectin has adverse effects".

38 *Ibid* at 339

39 Sanders, note 29 *supra* at 27 Sanders uses the idea of tradition asymmetrically. Tradition can be used to explain the otherwise unexplicated predominance of epidemiological evidence and its interpretation

> As a legal resource the in vivo studies were of increasingly little value in the face of a mounting body of epidemiological evidence. In a sense epidemiology drove out animal studies.[40]

Epidemiology is unable to speak for itself but requires interpretation, appropriation and legitimation by relevant and 'powerful' communities. Sanders quite rightly insists that the evidence was changing over time. However, he misses the finer and more important point that the negotiation and consensus over what were the most important and appropriate forms of evidence were also continuing. This deficiency is highlighted when Sanders, rather than identifying the diachronic construction of relatively 'stable' positions on certain types of 'evidence', describes the process as follows: "over time the courts would come to a more complete understanding of the facts of the cases".[41]

In Sanders' model, even though the legal system may have propelled Bendectin research, ultimately there were certain features of the life-cycle of Bendectin science over which the scientific community displayed autonomy. He argues that, whilst not all uncertainty regarding Bendectin's safety could be removed, the scientific community reached something approximating a consensus; that if Bendectin is a teratogen "it is a relatively mild one (having effects too subtle to be measured reliably with existing techniques)".[42] Sanders suggests that the scientific community, after achieving this consensus, felt that Bendectin had been 'overstudied', "and there arose the desire to *ration* Bendectin studies and save limited resources to study other drugs".[43]

In assessing the 'evidence' in the Bendectin litigation, Sanders concludes that "a number of factors distort scientific evidence presented at trial".[44] His proposed solution is the "presentation of scientific evidence in a manner that accurately conveys the *status* of scientific knowledge and increases the importance of scientific knowledge in the jury's determination of causation".[45] Similarly, Sanders offers a hierarchy of the various types of 'evidence' which resembles that eventually adopted by the majority of appellate courts. For example: "[*i*]*n vitro* evidence is superior to structure-activity evidence because it does investigate the effect of Bendectin ingredients."[46]

Why certain types of knowledge are more important than others and how they can be evaluated against one another is not decisively explained. Indeed these were the very controversies which courts were called to resolve throughout the Bendectin litigation. Sanders argues, under the Federal Rules of Evidence, that

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to support the safety of Bendectin: "A definitive case exonerating Bendectin or conclusively linking it to birth defects cannot be made. Still, the scientific findings disputing Bendectin's teratogenicity are substantial. If one employs *traditional* standards for proving the causal question, the science does not support a plaintiff's verdict." (emphasis added) 'Traditional' is seen as given and escapes closer examination.

40 Sanders, note 7 *supra* at 348.

41 *Ibid* at 377.

42 *Ibid* at 347.

43 *Ibid* citing L Holmes (emphasis in original)

44 Sanders, note 29 *supra*, p 60

45 *Ibid*, at 60-1 (emphasis added)

46 J Sanders, "Scientific Validity, Admissibility, and Mass Torts After *Daubert*" (1994) 78 *Minnesota Law Review* 1387 at 1409.

courts should not exclude "non-epidemiological evidence because *better* epidemiological evidence exists". Like the other commentators, Sanders mistakes the eventual consensus position, with its varying judicial and historiographical justifications, for some ontologically or epistemologically privileged position. These approaches are difficult to reconcile with a notion that law and science, by their nature and social authority, impact on each other's construction as well as being negotiated directly in legal forums, which will be developed below.

In a later paper,[47] Sanders contends that trials actually cause problems for the 'proper' evaluation of testimony. Indeed Sanders suggests that alternatives to the traditional civil jury should be examined to enhance 'fact-finding'. This aspect of Sanders' study again reveals his belief that epidemiological evidence was most important. The failure by a juror to agree with this assertion implicitly constitutes evidence of juror incompetence: "One juror [from the *Havner* litigation] even ranked epidemiology last in importance, behind animal studies, *in vitro*, and structure-activity evidence, respectively."[48]

Given Sanders' commitment to the value of epidemiology, he dedicates a small section to an examination of reasons why juries 'undervalued' epidemiology: "a defense of a product or toxic tort claim based on pure epidemiological evidence confronts an especially difficult task of persuasion."[49]

Instead of evaluating the divergent claims being offered by different witnesses and courts, Sanders attributes the inconsistency to the complexity of the epidemiology. Again, the ongoing negotiation and refinement of evidentiary standards is 'lost'.

Sanders concludes his most detailed analysis by applying a collection of categories to the various appellate cases. He divides the cases into those decided on 'legalistic', 'scientific' and 'legal-scientific' grounds. Without going into too much detail, Sanders assumes these categories are unproblematic, being relatively simple to apply.[50] However, the categories are reifications and exist in part as components of the judicial legitimation of decisions. Sanders describes the appellate decision in *Richardson*[51] as 'scientific' because it allegedly considered the "scientific underpinnings", whereas the appellate decision in *Oxendine I* is described as 'legalistic' because it used 'authority' from earlier cases. On closer inspection, we find (as will be explained in more detail in the case-study below) that the *Oxendine* court considered the 'scientific evidence' but came to a divergent conclusion over its relative value and that the *Richardson* court employed 'authority'. From our perspective, it is unfortunate that these categories only serve to perpetuate the positivist assumptions underlying Sanders' analysis.

For Huber, the story of Bendectin is a regrettable instance of the creation and ultimate deconstruction of 'junk science'. In contrast, Sanders recreates a more

47 Sanders, note 29 *supra* at 45

48 *Ibid*

49 *Ibid* at 60.

50 Sanders, note 7 *supra* at 378-9.

51 *Richardson by Richardson v Richardson Merrell Inc.* 857 F 2d 823 (DC Cir 1988)

complex account of the Bendectin story. His account suggested that there was a scientific consensus produced outside the court, that epidemiology in general as a scientific field had the power to establish causation ahead of other forms of scientific evidence. Further, Sanders argues that there was also a scientific consensus that epidemiological studies, in the specific case of Bendectin, did not establish causation. Both Huber's and Sanders' reconstructions are flawed. Huber's style of reconstruction relies on a highly artificial recreation of events and overlooks the internal dynamics and processes involved in the creation of toxicological scientific knowledge. This is typical of the reified images of science prevalent in 'junk science' discourse.[52] Sanders' reconstruction is more sociologically refined and displays some awareness of the way external pressures on science may play a role in the construction of scientific knowledge and its social interpretation.

We would contend that Sanders' reconstruction of the life-cycle of Bendectin science still displays a certain reluctance to acknowledge how 'deeply' the science in mass torts is 'shaped' by the various legal settings in which scientific knowledge is constructed. In particular, we contend that it is rather artificial to suggest that the primacy of epidemiology, or the development of a consensus based upon the epidemiology which suggested that Bendectin is relatively safe, were not contingent and contested 'conclusions'. Both Huber's and Sanders' reconstructions of the Bendectin litigation are strongly shaped by the benefit of hindsight. Whilst Sanders acknowledges a number of contingencies 'along the way', we would argue that these are still interpreted in the light of Sanders' knowledge at the time of writing. Sanders underplays the fluidity involved in the local construction of law-science knowledges. The 'life-cycle' of torts is a useful metaphor, but adopting more sophisticated approaches from the sociology and philosophy of science provides an important antidote for the tendency for the concept 'life-cycle' to be used 'too rigidly' or as a retrospective gloss. In particular, within the life-cycle of torts there will be numerous contradictory negotiations over the meanings of scientific knowledge. The image of a relatively autonomous consensus emanating from the scientific community should not be artificially reconstructed. Rather than consensus, it is better to assess the 'outcome' as the 'co-production' by both lawyers and scientists of a somewhat precarious and incomplete politically (legally) enforced 'closure'; a closure itself prone to further deconstruction and reconstitution in future law-science settings.

Similarly, though in far less detail, Green's analysis, which attempts to provide a detailed examination of evidence in *Agent Orange* and *Bendectin* litigation, exhibits a positivist outlook. Green explains that:

> In the science of toxicology, there are five different types of evidence that may contribute to an inference of causation: epidemiology, animal toxicology, in vitro testing, chemical structure analysis, and case reports. The most desirable evidence in epidemiologic.[53]

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52 See also G Edmond and D Mercer, "Manifest Destiny. Law and Science in America" (1996) 10 *Metascience* 40

53 Green, note 8 *supra*, at 646.

Green gives reasons for his preference for epidemiologic over non-epidemiologic forms of evidence, but does not explain how he can legitimately make the choice between their relative 'advantages' and 'disadvantages'.[54] Yet he reveals: "[t]here plainly is a hierarchy to these different indirect forms of toxic evidence. Epidemiology is at the top, and structural similarity, *in vitro* testing, and case reports are at the bottom."[55] These conclusions seem to draw significantly from Judge Weinstein's *Agent Orange* decision. Green's best insights come toward the end of his paper. Here he suggests that: "the Bendectin causation cases may better be viewed as an instance of the courts making a finding of legislative fact that Bendectin does not cause birth defects."[56] Such a perspective conveys a superior image of the need to link the social and epistemological factors in knowledge 'closure'. In furtherance of this approach, Green questioned the utility of peer review, publication standards and reliance on 'statistical significance' (for epidemiological studies) arguing that:

> one of the lessons of the Bendectin cases is that the courts are not truly engaging in greater scrutiny of experts' opinions; rather, they are adopting a few relatively simple screening devices.[57]

However, Green remained convinced that had courts actually engaged in epistemic scrutiny of the evidence, epidemiology would still have come to predominate. The problems caused by expert testimony leads Green, like Sanders, to suggest the use of court-appointed experts and science panels as solutions to law-science problems.[58] Green, too, is unable, or unwilling, to extend the implications of his analysis into the judicial construction of (and feedback into) legitimate forms of scientific knowledge.

Drawing from literature in the sociology of scientific knowledge, the observations of Sanders and Green can be extended to make a number of important theoretical observations concerning the 'co-production' of law-science knowledges.[59] Rather than interpreting a separation between scientific knowledge-making and the legal process in such contexts as the *Bendectin* litigation, it is beneficial to evaluate the 'science' and 'litigation' as part of the one knowledge making process. Some useful analogies may here be drawn between science involved in tort litigation and the development of law-science 'hybrids' such as forensic science.[60] It would appear to be inappropriate to dismiss the sort of scientific work involved in the *Bendectin* litigation as in some ways anomalous compared to the image of science produced outside of legal contexts.

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54 *Ibid* at 654.

55 *Ibid* at 658.

56 *Ibid* at 679.

57 *Ibid* at 694.

58 Cf G Edmond and D Mercer, "Keeping Junk History, Philosophy and Sociology of Science out of the Courtroom: Problems with the Reception of *Daubert v Merrell Dow Pharmaceuticals Inc*" (1997) 20 *UNSWLJ* 48 at 79-81

59 S Jasanoff, "Beyond Epistemology. Relativism and Engagement in the Politics of Science" (1996) 26 *Social Studies of Science* 393

60 R Smith and B Wynne (eds), *Expert Evidence: Interpreting Science in the Law*, Routledge (1989)

IV. CASE STUDY OF BENDECTIN: THE PRODUCTION OF LAW-SCIENCE KNOWLEDGE

For Huber, Lasagna, Shulman and Black, the Bendectin litigation exemplifies some of the pathological problems in the contemporary United States legal system. In a sense, this is surprising given that in their accounts in all but a few instances, 'genuine science' in the guise of published and peer reviewed epidemiological studies was ultimately accepted or upheld. Sanders, as we have seen, provided a considerable refinement on these positivist accounts which accommodates diachronic change in the nature of evidence and the administration of trials. However, despite this welcome contribution, Sanders infuses his more textured sociology with a positivist image of science; existing independently of law and legal contexts as a 'black box' which remains exempt from critical examination. As we have indicated, we believe Sander's account can be substantially improved by adopting a constructivist perspective toward scientific knowledge and incorporating the development of scientific-legal negotiation and consensus (which includes the articulation of knowledge claims in courts and administrative agencies) as part of the process of 'closure'. Such an approach provides a more fertile means of interpreting and explaining the enormous complexities involved in technological and scientific controversy. This approach also undermines the artificial ex post facto reconstructions where the eventual 'consensus' (closure) position (if one exists) is cast back over the entire controversy as a map to legitimate the eventual 'winners' as having always been 'obvious' and commensurate with the natural order.[61] This is what Huber, Black, Lasagna, Shulman, Sanders and Green have done, to varying degrees, in relation to the 'triumph' of epidemiology. They have assembled narratives which portray the ascendancy and primacy of epidemiological knowledge as inevitable.

The following case study is provided to illustrate the interpretative liberties these commentators have taken in constructing this simplistic linear account. A more refined analysis of various sites of Bendectin litigation provides insight into the way participants (parties, lawyers, judges and scientists) invoke a variety of resources to influence 'closure'. It should become evident from the breadth and duration of the litigation that what has been represented as eventually 'conclusive' can be seen as much more contingent and fragile, especially in the early 1980s. It should be noted that the type of selective history written by Black, Huber, Lasagna and Shulman has been employed by some of the participants in reversing plaintiff victories, affirming summary judgments or judgments notwithstanding the verdict for the defendant. As we shall see, courts upholding plaintiff 'victories' have adopted alternative strategies of legitimation.

Finally, the following study focuses upon the litigation surrounding Bendectin. We should make it clear that the purpose of the following discussion is not to engage for or against any particular side of the scientific controversy

61 H Butterfield, *The Whig Interpretation of History*, Bell (1931) ch 1,2

involving the teratogenicity of Bendectin.[62] However, we will examine the way, in a number of accounts (including appellate judgments) it was represented as inherently obvious that epidemiology was the most important branch of science in establishing causation. As we shall demonstrate, the eventual triumph cannot be seen as 'obvious' from the outset, nor unanimously accepted toward the decline in litigation. Similarly, the rise of epidemiology in Bendectin litigation cannot be understood divorced from its interaction with other contemporaneous large scale and public litigation (such as *Agent Orange*).

The following discussion will provide a chronological account of the 'key' *Bendectin* trials and appeals. Through exploring these cases in a chronological manner, the reader should acquire an awareness of the various processes involved in the diachronic construction of law-science knowledges. Below is a brief chronological table of the cases that will be considered.

Table 1

Year	Case	Court	Outcome
1983	Mekdeci	Appeal, 11th Cir	Jury finding for Merrell affirmed
1984	Koller	Appeal, DC Cir	Finding favouring Merrell
1985	MDL	Dist Ct	Plaintiff motion for jnov (see below) denied
1986	Oxendine I	Appeal, DC Cir	Reversed jnov for Merrell, Remanded
1986	Will	Dist Ct	Plaintiff motion for new trial and jnov denied
1986	Richardson	Dist Ct	Motion for jnov in favour of Merrell granted
1986	Lynch I	Dist Ct	Granted motion for summary judgment for Merrell
1987	Lynch II	Appeal, 1st Cir	Affirmed motion for summary judgment in favour of Merrell
1988	Richardson II	Appeal, DC Cir	Affirmed jnov in favour of Merrell
1988	Hull by Hull	Dist Ct	Summary judgment for Merrell granted
1988	In re Bendectin	Appeal, 6th Cir	Denied plaintiffs' motion for jnov in MDL jury trial
1989	Brock	Appeal, 5th Cir	Reversed jury verdict for plaintiff
1989	Brock	en banc hearing denied	Dissentient judgments
1989	Oxendine II	Appeal, DC Cir	Judgment reversed in favour of Plaintiff, Remanded

62 HM Collins, "Captives and Victims. Comment on Scott, Richards and Martin" (1991) 16 *Science. Technology & Human Values* 294, HM Collins, "In Praise of Futile Gestures: How Scientific is the Sociology of Scientific Knowledge" (1996) 26 *Social Studies of Science* 229, E Richards, "(Un)Boxing the Monster" (1996) 26 *Social Studies of Science* 323.

Year	Case	Court	Outcome
1990	Wilson	Appeal, 10th Cir	Affirmed jury verdict in favour of Merrell
1990	Bernhardt	Appeal, 5th Cir	Affirmed motion for summary judgment in favour of Merrell
1990	DeLuca	Appeal, 3rd Cir	Reversed and remanded summary judgment for Merrell
1990	Wilson	Appeal, 10th Cir	Affirmed jury verdict for Merrell
1990	Ealy	Appeal, DC Cir	Judgment in favour of plaintiff reversed
1990	In Re Bendectin	Dist Ct	Denied Merrell's motion for summary judgment
1990	Longmore	Dist Ct	Denied Merrell's motion for summary judgment
1990	Turpin	Dist Ct	Granted motion for summary judgment for Merrell
1990	Whelan	Dist Ct	Action dismissed, plaintiffs failed to show 'good cause'
1992	Elkins	Dist Ct	Granted motion for summary judgment for Merrell
1992	Turpin II	Appeal, 6th Cir	Affirmed motion for summary judgment in favour of Merrell
1992	Lee	Appeal, 6th Cir	Affirmed summary judgment in favour of Merrell
1993	Daubert	Supreme Court	'New' evidence standard provided, case remanded
1993	Raynor	Dist Ct	Granted jnov in favour of Merrell
1994	Wilson	Appeal, 10th Cir	Remanded for reconsideration after Daubert 93
1994	Oxendine IV	Appeal, DC Cir	Conditional affirmation of jury award, remanded
1995	Daubert II	Appeal, 9th Cir	Affirmed motion for summary judgment in favour of Merrell

jnov - judgment notwithstanding the verdict.

A. Unchartered Territory: The Early Trials

The early cases of *Mekdeci*,[63] *Koller*[64] and *Oxendine*[65] illustrate the complexity of mass torts and the uncertainties involved, especially at the 'beginning' of any litigation. In some capacity these cases were 'test' cases with

63 *Mekdeci by and through Mekdeci v Merrell National Labs Inc* 711 F 2d 1510 (11th Cir 1983).
64 *Koller by and through Koller v Richardson-Merrell* 737 F 2d 1038 (DC Cir 1984).
65 *Oxendine v Merrell Dow Pharmaceuticals Inc* 506 A 2d 1100 (DC App 1986)

tremendous significance for any potential subsequent litigation.[66] The trials of *Mekdeci* and *Oxendine* revealed the tentative and novel nature of the nascent *Bendectin* litigation. The 'universal' consensus described by commentators and expressed in later cases was absent; yet to be 'constructed'. Both courts allowed the plaintiffs' *in vivo, in vitro*, chemical structure analyses and epidemiological re-analyses to be admitted. In evaluating the cases, the jury in the *Mekdeci* trial appeared to produce a compromise verdict and the jury in *Oxendine* returned a verdict for the plaintiffs.[67] So, in the early 80's trial courts admitted evidence and juries rendered decisions favourable to plaintiffs. In attempting to explain these early 'successes', the accounts by the authors described above rely on conclusions of judicial incompetence and juries overwhelmed by emotion rather than the unfolding of a unique history where the law and science interacted over time and space to 'co-produce' 'legitimate' knowledge.

Given the admission of the plaintiffs' evidence in the early trials, a more fruitful analysis might examine what explanations were made concerning this admission and allowing the jury to decide on the facts during the trials and in appellate judgments. After the second *Mekdeci* trial (which returned a jury verdict for Merrell, the defendant) an appeal focused predominantly on the practices of the plaintiffs' lawyers. The appellate judges were content to accept the jury verdict, finding the various submissions of evidence admissible.

> The defendant [Merrell] says that the plaintiffs failed to present sufficient evidence to create a jury question on the issue of proximate cause. However, our disposition of the Mekdeci's appeal has the effect of affirming the jury verdict in the second trial, which absolved Merrell of liability in this action.[68]

The trial judge allowed the trial to proceed to full duration and the appellate court endorsed the finding of the jury.

Arguably, the most important of the early Bendectin trials was the Multi-District Litigation (MDL) in Ohio in 1985, involving over 800 plaintiffs.[69] Again the trial judge admitted both plaintiff and expert evidence pertaining to epidemiological and non-epidemiological knowledge. The trial was bifurcated into causation and damages. The causation trial was held first and the jury found in favour of Merrell. The judge found that "the jury's verdict was reasonable and not against the clear weight of the evidence".[70] Chief Judge Rubin noted that:

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66 Henderson and Eisenberg, note 2 *supra*; Saks, note 2 *supra*, Galanter, note 2 *supra*.

67 Jury assessment of complex evidence has been considered elsewhere: G Edmond and D Mercer, "Scientific Literacy and the Jury: Reconsidering Jury Competence" (1997) 6 *Public Understanding of Science* 1

68 Note 63 *supra* at 1523-4 (11th Cir 1983). See also *Will v Richardson-Merrell Inc* 647 F Supp 544 at 551 (SD Ga 1986) where in denying the plaintiffs' motion for judgment notwithstanding the verdict, Judge Edenfield emphasised the importance of jury verdicts: "Full respect must be given to the jury's findings and the judge must be careful not to usurp the prime function of the jury as trier of facts "

69 *In re Richardson-Merrel Inc "Bendectin" Products Liability Litigation* 624 F Supp 1212 (SD Ohio 1985) The judgment of Chief Judge Rubin was upheld by the 6th Circuit Court of Appeals in *In re Bendectin Litigation* 857 F 2d 290 (6th Cir 1988)

70 624 F Supp 1212 at 1244 (SD Ohio 1985).

> Both sides presented testimony of eminently qualified and highly credible experts who differed in regard to the safety of Bendectin. The jury was confronted with the classical task of any jury ie, assess the credibility of each witness and resolve all conflicts of fact.[71]

After the Multi-District Litigation, a 'shift' can be detected in the shape of much of the subsequent Bendectin litigation. The result in the massive MDL trial served as a source of legitimacy for defendants. Whilst the outcome of the MDL was obviously a 'blow' for the plaintiffs, there were a number of encouraging factors. In early 1986, the District of Columbia Court of Appeals reversed and remanded the Superior Court's grant of judgment notwithstanding the verdict and a new trial in favour of Merrell in *Oxendine v Merrell Dow Pharmaceuticals Inc* (*Oxendine I*).[72] The Oxendine appellate court effectively affirmed the uncertainty recognised by Rubin in the MDL:

> It is clear to the Court from review of the evidence adduced at the trial of this action that no conclusion one way or another can be drawn from any of the above relied upon bases, respecting whether Bendectin is a human teratogen.[73]

Unlike the majority of later appeals, *Oxendine I* exhibits a broad approach to the 'evidence'. Whilst acknowledging that the various components of the plaintiffs' scientific case were individually inconclusive, the court accepted that they might form more cogent evidence when combined.

> Like the pieces of a mosaic, the individual studies showed little or nothing when viewed separately from one another, but they combined to produce a whole that was greater than the sum of its parts.[74]

In adopting such a position the court was sceptical of the self-evident clarity which the defendants claimed concerning the epidemiological evidence. The court acknowledged what it conceived as genuine disagreement over the interpretation of the data and studies. In line with 'authority' from *Ferebee v Chevron Chemical Co,*[75] the *Oxendine I* court determined that such controversy should be left to the jury.

> Expert witnesses testified at length on both sides of that issue [causation]. Not surprisingly, their testimony revealed a disagreement as to how the epidemiological and other data should be interpreted. "The case was thus a classic battle of the experts, a battle in which the jury must decide the victor."[76]

The appellate court in *Oxendine I* shared the *Mekdeci* Court of Appeals' faith in the jury. In reversing the trial judge's judgment for Merrell notwithstanding the verdict, the District of Columbia Court of Appeals stated:

> It is clear from a review of the record that the verdict was not against the weight of the evidence. There was evidence on both sides on nearly every issue, and it was fairly evenly weighted.[77]

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71 *Ibid*
72 Note 65 *supra*.
73 *Ibid* at 1103.
74 *Ibid*. See also 1104.
75 736 F 2d 1529 (DC App 1984). See also Black, note 5 *supra*.
76 Note 65 *supra*.
77 *Ibid* at 1113.

And, not surprisingly, their testimony revealed a disagreement as to how the epidemiological and other data should be interpreted.[78]

In adopting this position the court emphasised the importance of the actual jury verdict.

> We must be particularly cautious about setting aside jury verdicts in cases such as this one, which present difficult medical issues of causation, with expert testimony going both ways.[79]

The court expressed reluctance to overturn a jury verdict with reasoning, also drawn from *Ferebee,* warning that judges have no special competence to resolve "complex and refractory causal issues".[80] In arriving at a position where it deemed the disagreement appropriate for the jury, the court identified 'limitations' to criticisms of the plaintiffs' evidence by Merrell. Criticisms of Done's approach were seen to be inadequately supported, and aspects of the *in vivo* and *in vitro* studies and chemical structure-activity analysis were effectively 'rescued'.[81]

B. Still Swinging Both Ways

The outcome of the Ohio Multi-District Litigation (MDL) served as a powerful resource for the defendant (Merrell) to attack persistent Bendectin litigants. One of Merrell's strategies was to argue that plaintiffs who had voluntarily opted out of the MDL were 'collaterally estopped' from re-litigating the issue of causation which the Ohio jury had found in favour of Merrell. Two of the implicit features of such an estoppel argument are that the cases to be tried are identical and that the 'evidence' remains effectively 'static' over time:[82] "In any trial, the same evidence would be presented to the fact finder."[83]

Of course, the estoppel argument was made in conjunction with assertions challenging the admissibility of the plaintiff's evidence (even though much of the 'evidence' had been deemed admissible in the MDL). By late 1986 in *Lynch v Merrell-National Laboratories*[84] this second approach was being framed as 'a matter of law', that is: "the plaintiffs' proof on the issue of causation is insufficient as a matter of law to establish causation".[85] The estoppel argument was overturned on appeal by the District Court of Massachusetts but the approach to establishing causation was upheld. The development of a 'crystallising' legal-epistemic position is a feature of legal processes which has received limited critical attention from legal scholars.[86]

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78 *Ibid* at 1110.

79 *Ibid.*

80 *Ibid* at 1104.

81 *Ibid* at 1111-12

82 *Brock v Merrell Dow Pharmaceuticals Inc* 874 F 2d 307 (5th Cir 1990) *Brock* offers some alternative where only new epidemiological evidence will afford reconsideration, though not based upon estoppel arguments, just admissibility and sufficiency.

83 *Lynch v Merrell-National Laboratories* 646 F Supp 856 at 862 (D Mass 1986)

84 *Ibid.*

85 *Ibid* at 857.

86 A Cambrosio, P Keating and M MacKenzie, "Scientific Practice in the Courtroom The Construction of Sociotechnical Identities in a Biotechnology Patent Dispute" (1990) 37 *Social Problems* 275;

The District Court in *Lynch* explained that the central issue:

> in any proceeding involving Bendectin and its role in birth defects is that of causation, and the issue has already been fully litigated in the consolidated trial [MDL].[87]

As this was a case which allegedly produced no new "medical or scientific opinion, no new studies, no new data or theories", the District Judge Mazzone was reluctant to allow the trial to continue or the plaintiffs' evidence to be admitted.[88] In so doing, the judge distinguished *Oxendine I*, explaining that that court did not possess the record of the consolidated (MDL) trial. It might seem surprising that Judge Mazzone could claim that the evidence was effectively the same in both cases (*Oxendine* and *Lynch*) and yet argue after the occurrence of the MDL trial that collateral estoppel is a doctrine capable of preventing the type of inconsistency which *Oxendine I* produced (even before it exemplified inconsistency through its use in *Lynch*). Inconsistency is a particular interpretation which gains rhetorical cogency after the MDL litigation. Judge Mazzone assessed *Oxendine I* by later standards, namely the later MDL which became a 'benchmark' in the evaluative repertoire of the participants.[89]

Judge Mazzone's decision to restrict the plaintiffs' evidence was founded upon "the important role epidemiological evidence may play in demonstrating illness or disease".[90] Yet such a position disguises the manner in which epidemiology had come to be the 'appropriate' means of making such determinations. Casting back to earlier *Bendectin* litigation, epidemiology assumed an important but not dominant status. The ascendancy of epidemiology appears to be partially drawn from the contemporaneous and very public *Agent Orange* litigation. Judge Weinstein found that "the only useful studies having any bearing on causation [in Agent Orange exposure]" were epidemiological. Mazzone endorsed this finding, claiming that "this conclusion is equally true with respect to the epidemiological studies of Bendectin".[91] In prioritising epidemiology, the court provided a mechanism for assessing evidence (or excluding certain types of 'evidence' outright) but was required to provide some justification for excluding or downplaying the 'reworked' epidemiology supplied by the plaintiff's experts.

In distinguishing the plaintiff's epidemiology, Mazzone adopted a mechanism which was re-used throughout much of the subsequent litigation. Plaintiff re-analysis studies were distinguished from the initial epidemiological studies. Part of the justification for depreciating the re-analyses was that these studies were

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B Campbell, "Generalists, Practitioners, and Intellectuals: the Credibility of Experts in English Patent Law" in R Smith and B Wynne (eds), *Expert Evidence: Interpreting Science in the Law*, Routledge (1989) 210.

87 Note 83 *supra* at 861.

88 *Ibid.*

89 Mulkay, note 1 *supra*; HM Collins and T Pinch, "The Construction of the Paranormal: Nothing Unscientific is Happening" in R Wallis (ed), *On the Margins of Science. The Social Construction of Rejected Knowledge*, Sociological Review Monograph 27 (1979) p 237.

90 Note 83 *supra* at 863

91 *Ibid.*

purportedly 'methodologically flawed' and "untrustworthy in that ... [they were] conducted during litigation". The court could not accept "result-oriented re-analysis of epidemiological studies and criticisms of others' methodology".[92] The implication of bias rather than the alleged methodological flaws was accentuated. The other forms of plaintiff evidence, such as chemical structure comparisons, *in vivo* and *in vitro* studies were criticised predominantly on the grounds that they were not susceptible to easy extrapolation to humans. Again, Weinstein's judgment from the *Agent Orange* litigation was cited:

> There is no evidence that plaintiffs were exposed to the far higher concentrations involved in both the animal and industrial exposure studies. The animal studies are not helpful in the instant case because they involve different biological species. They are of so little probative value as to be inadmissible.[93]

Chemical structure comparisons were seen to be "of even less probative value than the *in vivo* and *in vitro* animal studies".[94] Having 'disposed' of the plaintiffs' 'evidence', Judge Mazzone was able to conclude that:

> [t]he only relevant, probative, and non-misleading evidence on the issue of Bendectin's role in the causation of birth defects are the controlled observations of human beings, documented in more than 25 published epidemiological studies.[95]

Despite this confident judgment, there had been trials after *Oxendine I* where the jury preferred the plaintiffs' evidence. *Richardson v Richardson-Merrell Inc*[96] (*Richardson I*) was described as a "virtual reprise" of *Oxendine I*, and tried in the same circuit as the *Oxendine I* appeal. After a jury verdict for the plaintiffs, Merrell moved for judgment notwithstanding the verdict or a new trial. These motions were granted in the District Court. In distinguishing the appellate ruling in *Oxendine I*, District Judge Jackson contended that the appellate court had not addressed "the significance of certain evidence bearing upon the current state of scientific knowledge". But Judge Jackson went further, portraying a polarised view of the evidence "In consequence, it [*Oxendine I*] judicially reopened an esoteric twenty-year old controversy which is by now essentially settled within the scientific community."[97]

It was only a short step to the conclusion that "no reasonable jury could find ... that this infant plaintiff's birth defects were more likely than not to have been caused by her intra-uterine exposure to Bendectin".[98] Jackson provided a succinct overview of the tendered evidence. Merrell made use of about 25 published epidemiological studies which generally favoured their position whereas the plaintiffs relied upon re-analysis of epidemiological studies in conjunction with other types of evidence. In deriving his preference for the

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92 *Ibid* at 865.

93 *Ibid* at 866

94 *Ibid*

95 *Ibid* at 866-7

96 649 F Supp 799 (DDC 1986). Followed in *Raynor v Richardson-Merrell Inc* 1993 US Dist LEXIS 7498.

97 *Ibid* at 800 The acknowledgment of a long-standing debate works against Huber's simplistic account of the Bendectin debate as a 'recent' legal creation, note 4 *supra*

98 *Richardson I*, note 96 *supra*.

testimony submitted by Merrell, the judge drew on the importance of published and peer reviewed scientific literature.

> The totality of the scientific literature on the subject of Bendectin ... collectively represents the sum of all that can be said to be scientifically "known" of the matter at present. Excepting their own empirical observations, the "literature" is to scientists both the ultimate authority as to and the most respected repository of scientific knowledge.[99]

Plaintiffs endured and Merrell continued to assert its position by requesting motions for summary judgment on causation. *Hagen v Richardson-Merrell Inc*[100] was such an occasion. In dismissing the motion for summary judgment District Judge Norgle noted that, despite the "numerous other cases involving the same basic issues", those cases did "not bind this court or affect the court's independent analysis".[101] After a brief overview of the evidence, Judge Norgle decided that:

> The court finds material issues of fact clearly abound in this case. Substantial scientific evidence exists on both sides to support the conflicting arguments regarding causation.[102]

Alternatively there were cases where summary judgment was granted such as *Hull by Hull v Merrell Dow Pharmaceuticals Inc.*[103] Again Merrell argued that the plaintiff lacked sufficient evidence to prove Bendectin causes birth defects as 'a matter of law'. District Judge Gonzalez accepted this argument noting that:

> It is obvious to the Court that the plaintiffs cannot establish a causal relationship between Bendectin use and the occurrence of birth defects, particularly limb deformities. The body of scientific literature demonstrating the safety of Bendectin is extensive and overwhelming. More than thirty human epidemiological studies have been done and none have concluded that Bendectin is teratogenic.[104]

In supporting these claims, Judge Gonzalez referred to discussion on the importance of epidemiology drawn from *Lynch* and *Richardson*.

C. 'Authority' from the Circuit Courts of Appeal

From 1987 a series of appellate court decisions in a number of federal circuits went heavily against the plaintiffs. The first of these 'authoritative' appellate judgments was an appeal from summary judgment in *Lynch*, namely *Lynch v Merrell-National Laboratories*[105] (*Lynch II*). The court in *Lynch II* set the standard for the admission of evidence concerning alleged birth defects from Bendectin:

> A new study coming to a different conclusion and challenging the consensus would be admissible evidence. Without such a study there is nothing on which expert

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99 *Ibid* at 802 Compare Collins on 'tacit knowledge' and the TEA laser, note 26 *supra*, pp 56-7
100 697 F Supp 334 (ND Ill 1988).
101 *Ibid* at 336.
102 *Ibid* at 337.
103 700 F Supp 28 (SD Fla 1988).
104 *Ibid* at 29
105 830 F 2d 1190 (1st Cir 1987).

> opinion on Bendectin as a cause may be based. The plaintiffs offered no new study.[106]

In addressing the *in vitro, in vivo* and chemical structure analysis, the court cited Weinstein's *Agent Orange* judgement for the contention that:

> Studies of this sort, singly or in combination, do not have the capability of proving causation in human beings in the absence of any confirmatory epidemiological data.[107]

In making such strong claims the court felt compelled to provide its explanation of those cases which had been decided in favour of the plaintiffs.

> Our review would not be complete without consideration of cases in which jurors and judges - all reasonable men and women - have concluded that Bendectin is in fact a teratogen and have awarded damages against the defendant.[108]

Done's testimony concerning *in vivo*, *in vitro*, chemical studies and re-analysis of published epidemiological studies was deemed insufficient because of the court's a priori commitment to the primacy of epidemiology. This presupposition, central to the majority of cases, was rarely examined. In addition, the court found that Done's re-analysis had never been "refereed or published in any scientific journal or elsewhere" despite the acknowledgment that no flaw had been noted in *Oxendine I* or by the defendant in the case at hand.[109] In addition to these limited criticisms, the court undermined its description of judicial and juror 'reasonableness' by suggesting that the "sight of a helpless mutilated youngster may evoke emotion along with the corresponding wish to make someone pay for his or her plight".[110] These criticisms lead into the court's celebration of the District Court judgment:

> With this very real possibility of runaway emotion overcoming judgment, the District Court's firm rejection here of foundationless expert testimony was necessary, admirable and entirely within the discretion of the court under the Federal Rules of Evidence.[111]

The next circuit to rule against the plaintiffs' evidence was the DC circuit in the appeal from a judgment notwithstanding the verdict in favour of Merrell in *Richardson I.* The appellate court in *Richardson by Richardson v Richardson-Merrell Inc*[112] (*Richardson II*) affirmed the judgment, notwithstanding the verdict, of Judge Jackson in the District Court. Having explained that the quantum of evidence required was "sufficient evidence on which a jury could

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106 *Ibid* at 1194.

107 *Ibid* at 1194.

108 *Ibid* at 1195

109 *Ibid* at 1196.

110 *Ibid* It should be noted that such assumptions are against research on jury awards See VP Hans and WS Lofquist, "Jurors' Judgments of Business Liability in Tort Cases: Implications for the Litigation Explosion Debate" (1992) 26 *Law and Society Review* 85; E Greene, J Goodman and EF Loftus, "Jurors' Attitudes About the Size of Damage Awards" (1991) 40 *American University Law Review* 805, BJ Ostrom, DB Rottman and JA Goerdt, "A step above anecdote: a profile of the civil jury in the 1990s" (1996) 79 *Judicature* 233, Henderson and Eisenberg, note 2 *supra*, Saks, note 2 *supra*, Galanter, note 2 *supra*

111 *Lynch, ibid* at 1196-7

112 857 F 2d 823 (DC Cir 1988)

properly base a verdict for the Richardsons",[113] and providing an overview of the plaintiffs' evidence, the court concluded that in the face of an "overwhelming body of contradictory epidemiological evidence" the case lacked legal sufficiency.

> These three types of studies then - chemical, in vitro, and in vivo - cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.[114]

The court dispensed with Done's criticisms of the existing epidemiological studies, and his re-analysis of their conclusions, by noting his acceptance of the importance of 'statistical significance' and emphasising the gulf between a number of published epidemiological studies spanning a "significant period of time".[115] In contrast:

> [t]he studies rejected by Dr Done had been published in peer-reviewed scientific journals, while Dr Done has neither published his recalculations nor offered them for peer review.[116]

In addition, the appellate court made reference to the *Lynch II* and *Ferebee* decisions which had been decided in their own circuit. *Lynch II* was used to support the court's emphasis on the centrality of epidemiological evidence whilst dismissing the non-epidemiological evidence.

> The court [Lynch II] noted the growing body of law recognizing the importance of epidemiologic evidence in establishing causation in cases in which no direct evidence is available.[117]

Lynch II provided an authoritative resource for the DC Circuit to dismiss Done's testimony. It might be argued that the issue was more about determining what constituted 'acceptable' evidence in these settings rather than whether such 'evidence' existed. *Ferebee*, in contrast, necessitated some distinction because in that case the primacy of epidemiology over non-epidemiological evidence was not emphatically accepted.

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113 *Ibid* at 828

114 *Ibid* at 830 Compare the reasoning in the subsequent case of *Longmore v Merrell Dow Pharmaceuticals Inc* 737 F Supp 1117 at 1120 (D Idaho 1990) Senior District Court Judge Callister noted limitations to epidemiological studies in explaining causation. He found the approaches in other circuits in *Ealy, Richardson* and *Brock* non-compelling "This court does not mean to imply that epidemiological studies are without worth in proving causation. Certainly they play an important role ... A jury might find the studies conclusive But this court cannot - at this stage of the case - find the epidemiological evidence 'overwhelming' . Once the epidemiological evidence is stripped of its 'overwhelming' label, does Rule 703 still preclude the plaintiffs' expert testimony? Only if animal studies and chemical analyses are not reasonably relied upon by experts who attempt to investigate the connection between drugs and birth defects And the court cannot make such a finding on the basis of the record before it."

115 *Ibid*

116 *Ibid* at 831

117 *Ibid* (emphasis added). It is ironic that the court celebrated the value of epidemiology in this context where there is supposedly no direct evidence, yet at other points (such as in *Brock*) epidemiology is deemed to be crucial in determining the matter where there is uncertainty, but direct evidence In the various judgments the status and use of epidemiology is interpreted in a number of contradictory ways.

> 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. 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 to complete sophisticated laboratory studies of the chemical.[118]

The court ultimately interpreted *Ferebee*, including the above passage, to stand for the proposition that:

> courts should be very reluctant to alter a jury's verdict when the causation issue is novel and *'stand[s] at the frontier of current medical and epidemiological inquiry.*[119]

Noting that the *Oxendine I* court had also cited *Ferebee*, there was disagreement over what constituted a case on the 'frontier' of medical and epidemiological inquiry. Concluding that the case before them was unlike *Ferebee,* the Court of Appeals explained that the "twenty years of scientific study, and the published results must be given their just due". 'Recognition' of the conclusiveness of such overwhelming 'evidence' was presented as a component of judicial vigilance; to ensure that "neither emotion nor confusion has supplanted reason" and expressed in direct acknowledgment of "the importance of the jury's role in the legal system",[120] a role, however, the judge and appellate court both willingly usurped.

The next circuit to decide on Bendectin and birth defects was the Fifth Circuit Court of Appeals in *Brock v Merrell Dow Pharmaceuticals Inc.*[121] The *Brock* court commenced their consideration of the issues by claiming that abstract formulations concerning the sufficiency of evidence lose much of their utility through attempts at application and cause special problems for juries.[122] They explained that:

> One certainly might infer from the evidence in the case that Bendectin causes birth defects, and further that Bendectin caused Rachel Brock's limb reduction defect - in fact, the jury concluded that this very thing occurred. However, the court must determine whether this is a *reasonable* inference to be drawn from the evidence presented, and the formulae provide us with little guidance as to what constitutes a

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118 *Ibid* at 823

119 *Ibid* citing *Ferebee v Chevron Chemical Co*, note 75 *supra* at 1534 (emphasis in original).

120 *Ibid.*

121 Note 82 *supra.* Followed in *LeBlanc v Merrell Dow Pharmaceuticals Inc*, 1996 US Dist LEXIS 759 "The court [in *Brock*] found this lack of 'statistically significant' epidemiological proof that Bendectin causes limb reduction defects to be fatal to [plaintiffs'] case. . The Court stated that it expected its opinion to 'have precedential effect'". Contrast *Christopherson v Allied-Signal Corporation* 902 F 2d 362 (5th Cir 1990) at 367: "Courts have not required the proof or expert testimony concerning causation in toxic tort cases to be supported by epidemiological studies establishing a cause-effect relationship . The exception from this rule is this court's recent holding that absent statistically significant epidemiological proof that the drug Bendectin is a human teratogen, a plaintiff's proof that the drug caused her child's birth defects was insufficient [*Brock*] ... The court, however, specifically declined to hold that 'epidemiologic proof is a necessary element in all toxic tort cases'", *Barton v Richardson-Merrell Inc*, 1990 US Dist LEXIS 8010. Having allowed a jury trial which was inconclusive, Judge Jenkins eventually gave a directed verdict to Merrell following *Brock*, *Richardson* and *Lynch.*

122 Note 82 *supra* at 308-9.

> reasonable, as opposed to an unreasonable, inference that a jury could draw from the evidence.[123]

The problem was accentuated by the lack of "consensus in the medical community regarding whether a given substance is teratogenic; this is the case with Bendectin." Such uncertainty was seen to lead the jury to "resort to speculation".[124] The threat of uncertainty and the implications for society and manufacturers of inconsistent legal outcomes (implicitly inconsistent jury outcomes) was framed as a justification for judicial intervention in mass torts.

> Moreover, in mass torts the same issue is often presented over and over to juries in different cases, and the juries often split both ways on the issue. The effect of this is to create a state of uncertainty among manufacturers contemplating the research and development of new, and potentially lifesaving drugs. Appellate courts, if they take the lead in resolving those questions upon which juries will go both ways, can reduce some of the uncertainty which can tend to produce a sub-optimal amount of new drug development.[125]

The Firth Circuit Court of Appeals supported its approach by the 'precedent' of the recently conducted Agent Orange Litigation. Notice that the court suggests that judicial resolution of uncertainty removes a 'social problem'. The epistemological uncertainty may remain but it is transported into a legal solution. The use of non-participatory forms of resolution might be seen as undesirable or disconcerting.

In rendering its decision, the *Brock* court distinguished *Ferebee* as a court not "so willing to analyse the reasoning employed by experts to reach their conclusions".[126] They acknowledged *Ferebee's* recognition that judges held "no special competence to resolve the complex and refractory causal issues" on questions at "the frontier of current medical and epidemiological inquiry".[127] However, the court acknowledged that other Circuit appellate courts had "retreated from this approach recently".[128] The Court of Appeals explained that in *Richardson II* the court did not perceive its hands to be "inexorably tied" by experts, and interpreted the frontiers of medical science, from *Ferebee*, restrictively. The *Brock* court revealed their preference for following the *Richardson II* approach.[129]

In its examination of the sufficiency of the evidence presented, the *Brock* court stated that, "[u]ndoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies".[130] And, later: "speculation unconfirmed by epidemiologic proof cannot form the basis for causation in a court of law".[131]

The court cited a tradition of legal recognition of the importance of epidemiology dating from the early 1980s: "[w]e are not the first court to

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123 *Ibid* at 309, (emphasis in the original).
124 *Ibid.*
125 *Ibid* at 310.
126 *Ibid.*
127 *Ibid* at 311
128 *Ibid*
129 *Ibid.*
130 *Ibid.*
131 *Ibid* at 315.

emphasize the importance of epidemiologic analysis".[132] But the tradition did not extend to any epidemiological study. The *Brock* court refined what was considered 'acceptable' through its preference for published and peer reviewed studies.

> While we do not hold that this failure, in and of itself, renders his [plaintiff expert Dr Glasser] conclusions inadmissible, courts must nonetheless be especially skeptical of medical and other scientific evidence that has not been subjected to thorough peer review.[133]

Not only did the court 'discover' a tradition (within the circuit) recognising epidemiology as an important form of evidence, they also 'found' 'authority' exposing the limited usefulness of animal studies to questions of toxicity.[134] There follows a restricted review of limitations to extrapolations from animal studies.[135]

In addition, the court provided a prescriptive conclusion concerning the future of Bendectin and toxic tort litigation in the circuit.

> We expect that our decision here will have a precedential effect on other cases pending in this circuit which allege Bendectin as the cause of birth defects. Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiologic proof to be especially vigilant in scrutinizing the basis, reasoning and conclusiveness of studies presented by both sides.[136]

Only 'new' and 'conclusive' epidemiological studies would provide a sufficient basis for allowing cases to go before a jury. New did not include unpublished re-analysis.

One of the judges in the Fifth Circuit polled the other judges for a rehearing of *Brock* en banc. The majority of the judges voted against the request, though six judges offered a strong dissent. Among the concerns of the dissentient judges was the apparent erosion of the Seventh Amendment right to a trial by jury and the characterisation of the plaintiffs' "voluminous expert proof as 'speculation'", suggesting an impending doom for virtually all expert testimony.[137] The strongest criticism was directed at the predominance of epidemiological evidence.

> The panel reaches its climax with the novel declaration that only epidemiological studies can prove causal relation between Bendectin and birth defects ... In the absence of expert consensus must we always await population studies before a jury verdict may be based upon medical opinion? So says the panel, at least for Bendectin cases. This, despite the testimony here that case reports and laboratory research reveal that no epidemiological study has ever discovered a teratogen.[138]

The dissentients also cryptically distinguished *Richardson*.

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132 *Heyman v United States* 506 F Supp 1145 (SD Fl 1981).

133 Note 82 *supra* at 313.

134 *Gulf South Insulation v US Consumer Product Safety Commission* 701 F 2d 1137 (5th Cir 1983).

135 Note 82 *supra* at 313-14.

136 *Ibid* at 315 This and another paragraph in the judgment were modified to emphasise the importance of statistically significant epidemiological studies in *Brock v Merrell Dow Pharmaceuticals* note 82 *supra*.

137 *Brock*, note 82 *supra*.

138 *Ibid* at 168.

Slowly a 'position' was emerging providing authority for other courts. Courts appeared to find it increasingly easier to dismiss plaintiffs' claims based on authority from other circuits, rather than justification derived from detailed examination of the 'evidence'. In the Tenth Circuit Court of Appeals case of *Wilson v Merrell Dow Pharmaceuticals Inc*,[139] the court concluded that:

> Merrell Dow presented expert testimony, which was not contradicted by the Wilsons' experts, that of the approximately forty epidemiological studies of Bendectin, none has shown a statistically significant association between the ingestion of the drug and the incidence of birth defects generally or limb defects in particular. This lack of epidemiological proof for the Wilson's claims is particularly significant in light of recent decisions of federal courts of appeals [Brock, Richardson, Lynch] granting judgment [notwithstanding the verdict] for Merrell Dow based upon the absence of epidemiological evidence showing a causal relationship between Bendectin use and birth defects.[140]

An appeal to the Fifth Circuit Court of Appeals in *Bernhardt v Richardson-Merrell Inc*,[141] displays a similarly dismissive approach to the plaintiffs' appeal against summary judgment supposedly compelled by an earlier decision.

> There is no question of material fact ... We do not broach the broader questions whether Bendectin is a human teratogen, although if we did so, we would be bound by our court's prior holding in Brock v Merrell Dow Pharmaceuticals Inc , 874 F 2d 307 (5th Cir 1989).[142]

In disposing of the appeal in *Ealy v Richardson Merrell Inc*,[143] the DC Circuit Court of Appeals relied heavily upon the authority of *Richardson* decided earlier in the same circuit.

> We find that this case is squarely within the binding rule articulated in Richardson: an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of "a wealth of published epidemiological data" to the contrary ... Accordingly such expert opinion is inadmissible.[144]

In utilising authority in this manner the court differentiated earlier cases, particularly *Oxendine I,* by noting that fewer scientific studies were introduced in the earlier cases.[145] *Richardson* was drawn upon to emphasise the importance of the "overwhelming body of contradictory epidemiological evidence" developed over a "significant period of time".[146] Again relying heavily upon *Richardson*, the *Ealy* court also found the "battle of the experts" and the theory

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139 893 F 2d 1149 (10th Cir 1990)

140 *Ibid* at 1154. After an interlocutory appeal, pending *Daubert v Merrell Dow Pharmaceuticals Inc* 113 S Ct 2786, summary judgment was denied and the case was remanded to the district court: *Wilson v Merrell Dow Pharmaceuticals Inc* 20 F 3d 379 (10th Cir 1994)

141 892 F 2d 440 (5th Cir 1990).

142 *Ibid* at 445.

143 897 F 2d 1159 (DC Cir 1990). Followed in *Whelan v Merrell Dow Pharmaceuticals Inc* 1900 US Dist 11504 (DC): "First, despite plaintiffs' protestations to the contrary, this Court is bound by the holdings in *Richardson* and *Ealy*. This Circuit has found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, *in vivo* studies, *in vitro* studies, or reformulated epidemiological data, is not admissible "

144 *Ibid*

145 *Ibid* at 1163.

146 *Ibid* at 1161.

of causation standing at the "frontier of current medical and epidemiological inquiry", drawn from *Ferebee*, inapposite.[147]

As a matter of law, the *Ealy* court found Bendectin to be non-teratogenic.

> Therefore, under Rule 703, an opinion refuting this scientific consensus is inadmissible for lack of an adequate foundation, in the absence of other substantial probative evidence on which to base this opinion. It is this uncontroversial rule of evidence that is the ratio decidendi of Richardson and this case.[148]

Citing *Lynch, Brock* and the Agent Orange Litigation, the court reinforced the importance of epidemiology and the strength of epidemiological evidence in the instant proceedings.

> The body of published epidemiological opinions on the subject at hand is extensive, indeed massive, and all such opinions point to the same conclusion. As Richardson teaches, this is our measuring rod for scientific adequacy.[149]

In contrast, epidemiological re-analysis, *in vivo, in vitro* and chemical structure analysis were seen as 'dubious': "This data, however, along with all the other *in vivo, in vitro,* and chemical structure data, has dubious significance in the face of epidemiological data".[150]

In addition, the *Ealy* court found that the inadequacy of the plaintiffs' evidence had been accentuated by two large epidemiological studies (published after *Oxendine I* and *Richardson)* which found no association between Bendectin and birth defects. The case was remanded for judgment in favour of Merrell, notwithstanding the verdict and an initial jury award of $95 million.

The next of the appeals was *DeLuca v Merrell Dow Pharmaceuticals Inc.*[151] *DeLuca* was an appeal from summary judgment against the plaintiffs in the District Court of New Jersey. Despite an ever growing body of 'authority' the decision went in favour of the plaintiffs. The court was critical of Merrell's approach to the trial. The decision revealed a belief that Merrell had not provided adequate criticism to warrant the exclusion of evidence from the plaintiffs' expert (Done):

> Nor did it address the specific methodology and reasoning underlying Dr Done's conclusion that Bendectin is a teratogen. Instead, Merrell Dow relied upon the great weight of scientific opinion in its favour and upon prior cases in which testimony that Bendectin is a teratogen was held to be inadmissible or insufficient to support a verdict. This was consistent with its apparent litigation strategy which was to emphasize that "[i]n all material respects, the instant case is identical to the cases where summary judgment has been granted in Merrell Dow's favour".[152]

Whereas other courts had generally emphasised the importance of the 'great weight' of evidence, the *DeLuca* court sought to demonstrate why certain approaches were 'inappropriate', that is, methodologically unsound. The court

147 *Ibid* at 1162
148 *Ibid*
149 *Ibid*, (emphasis in original)
150 *Ibid* at 1163
151 911 F 2d 941 (3rd Cir 1990).
152 *Ibid* at 944.

claimed to be unwilling to confer authority on the position held by the 'majority' of scientists in the absence of arguments against the minority position.

Despite its criticism of Merrell's 'strategy', the court revealed that the DeLucas were compelled to rely upon "inferences drawn from epidemiological data to show causation in Amy's [the plaintiff] case."[153] However the court recognised that the controversy itself was partially focused on the appropriate means of interpreting the existing epidemiological data; the very data relied upon by Merrell and the FDA. Done's approach, drawn from work by Professor Rothman, placed "diminished weight on so-called 'significance testing'".[154] The arbitrary nature of a .05 level of statistical significance was recognised and discussed.[155] However, Done's failure to quantify his re-analysis along with its non-publication and peer-review were acknowledged.[156]

Whilst downplaying the Bendectin case-law, the court considered that a review would aid their determination. They noted that Judge Rubin (from the Ohio MDL) believed that both sides possessed "eminently qualified and highly credible experts who differed in regard to the safety of Bendectin," and acknowledged Done's 'mosaic theory' from *Oxendine I.* In reviewing *Lynch II* and *Richardson*, the court explained how plaintiffs' evidence was not only seen as insufficient to support a verdict, but inadmissible under the Federal Rules of Evidence (1975). Each court held that only "a new epidemiological study concluding that Bendectin was associated in a statistically significant way with an increase in birth defects" would be admissible. In adopting this position, each court "placed a heavy emphasis on the large number of epidemiological studies ... in the scientific literature".[157] The Third Circuit Court of Appeals distinguished *Brock* from these two other appellate court decisions, although it eventually arrived "at the same destination". *Brock* had emphasised concern over legal inconsistency and its impact on manufacturers but the court did not deem the plaintiffs' expert testimony that Bendectin was a teratogen inadmissible.

> Instead, the court held that their evidence was insufficient to sustain a verdict absent "statistically significant epidemiological proof that Bendectin causes limb reduction defects"[158]

In contrast, the *DeLuca* court was critical of the approach taken by the *Brock* court. Their comments indicate a 'dynamic' negotiation of the appropriate evidentiary standards.

> The court [Brock] purported to base its decision on a critical analysis of the reasoning of the plaintiff's experts but it did not explain the basis for its holding that statistically significant epidemiological results were required to sustain a verdict in plaintiff's favour.[159]

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153 *Ibid* at 945.
154 *Ibid* at 946
155 *Ibid* at 947
156 *Ibid* at 949
157 *Ibid* at 950.
158 *Ibid* at 951.
159 *Ibid.*

Further, the *DeLuca* court referred to Judge Rubin's recent denial of a motion from Merrell for summary judgment in another consolidated trial and the dissentients after the vote against the en banc hearing in *Brock*.[160] Judge Rubin had denied the motion:

> because he found a division in the scientific community as to whether epidemiological evidence was the only type of evidence that could reliably link Bendectin to an increased risk of birth defects, and he refused to substitute his judgment for experts in the relevant fields or to decide, instead of the jury, which view was the more reasonable. Thus, he denied Merrell Dow's assertion that the plaintiff's expert evidence, which was based on epidemiological evidence as well as structure activity analysis, and in vitro and in vivo studies was inadmissible or insufficient to create a genuine issue of material fact.[161]

Further the *DeLuca* court expressed its inability to make special rules to address the problems posed by Bendectin litigation. They were unable to preclude issues from litigation; even those which had been previously thoroughly litigated. They explained that the Federal Rules of Evidence contained no requirement that expert testimony be subject to peer-review and publication in the professional literature.[162] The court accepted that epidemiology was a subject fit for judicial notice, citing the *Agent Orange* litigation, but then considered whether Done's re-analysis was admissible. In deciding, they drew upon authority from the *United States v Downing*,[163] to reject the general acceptance test of *Frye v United States*,[164] in preference for assessing the evidence based on its soundness and reliability, and acknowledging that there are dangers of the jury being overwhelmed if forced to consider the proffered connection between the research and the disputed factual issues. Whilst the weight of scientific opinion was not wholly irrelevant, the opinion could not be excluded simply because the "weight of scientific opinion was against him".[165] In remanding the case the court explained its central concern: "The root issue it poses is what risk of what type of error [for epidemiological studies] the judicial system is willing to tolerate."[166]

In making its decision the Court of Appeals reminded the court of remand that the Federal Rules of Evidence "embody a strong and undeniable preference for admitting evidence having some potential for assisting the trier of fact and for dealing with the risk of error through the adversary process".[167] In deciding on the admissibility of Done's evidence the court explained:

> his testimony goes to the crucial issue of causation, and his analysis purports to be based on a theory of epidemiological reasoning that has support in the published literature.[168]

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160 *In re Bendectin Products Liability Litigation* 732 F Supp 744 (ED Mich 1990).
161 Note 151 *supra* at 951
162 *Ibid* at 954
163 753 F 2d 1224 (3rd Cir 1985)
164 293 Fed 1013 (DC Cir 1923) See also note 58 *supra*
165 Note 151 *supra* at 955. See also 956.
166 *Ibid*
167 *Ibid* at 956.
168 *Ibid* at 957

In the absence of countervailing evidence they were unwilling to conclude his testimony would be unhelpful. Without further testimony from experts critiquing Done's analysis the court expressed a lack of confidence in determining the issue and therefore a reluctance to exclude Done's testimony.[169]

The Ninth Circuit Court of Appeals initiated its review of a Bendectin case disposed by summary judgment, *Daubert v Merrell Dow Pharmaceuticals Inc*,[170] destined to go to the United States Supreme Court, by affirming the *Frye* test which required that expert scientific opinion "is admissible if it is generally accepted as a reliable technique among the scientific community".[171] The court then referred to the history of Bendectin litigation to emphasise that three of the four other circuits had considered the matter and could not, "in the absence of critically analysed epidemiological studies ... [establish] a connection between the use of the drug and the birth defects." [172]

> Considering largely the same evidence presented to the district court below, these courts held that the animal studies and chemical studies were insufficient to establish a link between Bendectin and birth defects ... These courts were unwilling to allow plaintiffs to rely on reanalyses of epidemiological studies because these reanalyses had neither been published nor subjected to the rigors of peer review. They found the methodology particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny of the scientific community.[173]

The *Daubert* court explained that re-analysis was accepted in the scientific community "only when it is subject to verification and scrutiny by others in the field".[174]

> Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process and generated solely for use in litigation.[175]

This position seems to have been supported, in part, by Huber's polemical writings. His naive images of science were appropriated by the court to facilitate and legitimate the exclusion of certain knowledge claims. The court cited Huber for authority that "[t]he best test of certainty we have is good science - the science of publication, replication, and verification, the science of consensus and peer review".[176]

The use of Huber's work in actual judgments raises an important issue involving the permeability of boundaries between legal decision-making, academic and populist commentary and scientific discourse. The existence of such 'feedback loops' and self-referential discourse within the judgments in the

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169 *Ibid* at 957, 959.

170 951 F 2d 1128 (9th Cir 1991) This decision has stimulated a huge and important debate in the legal and social science literature. See Edmond and Mercer, note 58 *supra*, for a comprehensive discussion.

171 *Ibid* at 1129 citing *United States v Solomon* 753 F 2d 1522 (9th Cir 1985) at 1526.

172 *Ibid* at 1130 citing *Brock*, *Richardson*, and *Lynch*.

173 *Ibid.*

174 *Ibid* at 1131.

175 *Ibid*

176 *Ibid.* See also Huber, note 4 supra, p 228. See also K Chesebro, "Galileo's Retort Peter Huber's Junk Scholarship" (1993) 42 *American University Law Review* 1637; Edmond and Mercer, note 52 *supra*

Bendectin litigation highlight the importance of attempting to produce a diachronic account of the processes involved in negotiating law-science knowledge in mass toxic torts. Epistemologically neat, synchronic reconstructions overlook these important processes.

E. Turpin and Daubert as Consolidated 'Authority'

Turpin v Merrell Dow Pharmaceuticals Inc[177] was an appeal from summary judgment handed down by Chief Judge Siler in ED Kentucky District Court. Siler held that experts could not rely on "animal studies, analogous chemical studies, and criticisms of epidemiologic data in forming their opinion as to prescription drug's teratogenicity".[178] Siler claimed that "no genuine issues of "material fact exist and the case can therefore be decided as a matter of law."[179] On appeal the Sixth Circuit Court of Appeals commenced its decision with a policy comment on the importance of consistency in litigation.

> For a judicial system founded on the premise that justice and consistency are related ideas, the inconsistent results reached by courts and juries nationwide on the question of causation in Bendectin birth defects cases are of serious concern.[180]

The court stressed the importance of "inspecting the reasoning of qualified scientific experts".[181] They outlined their intention to examine both the evidence for causation and the case-law "in greater detail" than earlier courts and "show why it does not meet the legal test of causation".[182]

Despite the purported similarity in the Bendectin cases, described as 'variations on a theme' or an 'orchestra which travels to different music halls', the court was disturbed to find such diversity, although they could only identify one case finally upholding a finding of causation: *Oxendine I.* They contrasted *Oxendine I* with a number of jury findings for Merrell.[183] "More importantly", they noted that four federal circuits held "that plaintiffs failed as a matter of law to establish causation of birth defects".[184] The court drew on *Brock* as a

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177 959 F 2d 1349 (6th Cir 1992) Followed in *Lee v Richardson-Merrell Inc* 1992 US App LEXIS 8478 (6th Cir 1992): "We conclude that a finding of a causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin v Merrell Dow Pharmaceuticals Inc* .. In *Turpin*, another panel of this court reviewed the scientific data on Bendectin in great detail and concluded that the evidence presented by the plaintiff's experts fell short of showing that 'Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at the prescribed doses during pregnancy'"; *Elkins Richardson-Merrell Inc*, 842 F Supp 996 at 998 (1992): "The Court of Appeals held that the animal studies relied upon by plaintiff's experts did not prove causation in humans Here, the record's explanation of animal studies is simply inadequate Although the animal studies themselves may have been scientifically performed, the exact nature of these tests is explained only in general terms "

178 *Turpin v Merrell Dow Pharmaceuticals Inc* 736 F Supp 737 (ED Ky 1990)

179 *Ibid* at 737-8

180 Note 177 *supra* See also 1351

181 *Ibid.*

182 *Ibid* at 1350.

183 *Wilson v Merrell Dow Pharmaceuticals* note 139 *supra*, *Will v Richardson-Merrell Inc* 647 F Supp 544 (SD Ga 1986), *In re Richardson Merrell Inc "Bendectin" Products Liability Litigation* 624 F Supp 1212 (SD Ohio 1985), note 69 *supra*; *Cosgrove v Merrell Dow Pharmaceuticals Inc* 788 P 2d 1293 (1990).

184 Note 177 *supra* at 1351.

judgment notwithstanding the verdict; *Daubert* affirming a grant of summary judgment; and *Richardson* (and *Ealy*) and *Lynch II* on the grounds that the plaintiffs' evidence was inadmissible. Four district courts had granted summary judgment and eight courts had either denied summary judgment for Merrell or reversed on appeal.[185]

> The fundamental reasons for the inconsistency of the legal system in handling Bendectin claims appear to be first, the difficulty of scientists and hence of judges, lawyers and jurors in knowing what reasonable inferences of causation to draw from animal experiments and epidemiological studies; and second, the uncertainty of judges about how far they should enter the scientific thicket of conflicting inferences.[186]

Judicial scrutiny of scientific evidence was required because of the "likelihood of juror misunderstanding" and because of the potential biases of scientists paid for their testimony.

The plaintiffs had tendered *in vivo, in vitro,* chemical structure analyses and the re-analysis of epidemiological data. The defendant relied predominantly upon epidemiology (now 35 studies) but also combined secular trend data[187] which they argued showed no decline in the incidence of birth defects with the withdrawal of Bendectin from the market. In assessing the evidence, the court considered the plaintiffs' challenge to the epidemiological proof and the strength of the animal studies.

The appellate court in *Turpin* provides one of the few occasions where the plaintiffs' concerns about epidemiology were treated 'seriously'. The court recognised that there might be methodological problems associated with some of the issues the plaintiffs' had expressed. These included: that the 35 studies were based on samples too small to prove the absence of causation, "in light of the infrequency of instances of birth defects"; that the studies do not adequately distinguish limb from non-limb defects; the studies do not control for confounding factors such as smoking and other drugs; whether an arbitrary .05 statistical significance has any relevance for legal settings and any relation to the "preponderance of the evidence standard of proof"; and that some of the studies could be interpreted to show some statistically significant relationships in favour of the plaintiffs' case if lower levels of certainty were applied. Whilst acknowledging that the defendant's evidence was capable of sustaining a verdict, the court agreed "with the plaintiffs' experts that this evidence, was by no means conclusive".[188]

> The science of epidemiology is currently unable to identify the causes of many birth defects or to exclude from consideration many possible causes, including Bendectin and a host of other outside agents and environmental factors.[189]

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185 *Ibid* at 1352.

186 *Ibid.*

187 'Secular trend data' refers to the incidence of limb deformation after Bendectin was removed from the market. It provides a comparison with the incidence of deformation when Bendectin was in use See also *Wilson v Merrell Dow Pharmaceuticals Inc* note 139 *supra*

188 Note 177 *supra* at 1356-7.

189 *Ibid* at 1358.

In regard to the *in vitro* studies, the court found that the evidence suggested that Bendectin was "capable of causing" limb defects in humans, not that it did cause such defects. Similarly, *in vivo* results were seen to have the capacity to cause defects at higher dosages in animals but experts could not confidently extrapolate that Bendectin did cause such effects at normal dosages. This led the court to conclude that:

> The decisive weakness in the plaintiffs' animal studies is that the factual and theoretical bases articulated for the scientific opinions stated will not support a finding that Bendectin more probably than not caused the birth defect here.[190]

Unlike many of the earlier decisions, the court was unwilling to dismiss non-epidemiological knowledges.

> We do not mean to intimate that animal studies lack scientific merit or power when it comes to predicting outcomes in humans. Animal studies often comprise the back-bone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies.[191]

Ultimately the decision came down to the 'analytical gap' between the animal experiments and inferences capable of being drawn pertaining to humans being too wide to sustain a jury verdict.

In 1993 the issue of the appropriate standard for the admission of expert opinion evidence under the Federal Rules of Evidence went to the United States Supreme Court in *Daubert v Merrell Dow Pharmaceuticals Inc.*[192] The Supreme Court supported its rejection of the *Frye* 'general acceptance' test and its replacement with more stringent judicial 'examination' of scientific evidence with the appellate decisions of *Turpin* and *Brock*. The Court explained that conventional approaches such as viewing the evidence of credible witnesses as admissible but insufficient were "the appropriate safeguards" for preventing a "'free-for-all' in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions".[193]

On remand to the Ninth Circuit Court of Appeals summary judgment for Merrell was affirmed.[194] The court expressed its concern at having to enter scientific debates and determine what constituted 'good science', preferring the "relatively simple", though now (federally) defunct, *Frye* general acceptance test.[195] In arriving at its decision, the court seems to have repeated many of its earlier approaches. They were sceptical of research conducted for litigation: "a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office."[196] Similarly, publication and peer review were seen as central

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190 *Ibid* at 1359 Dr Palmer testified that he believed Bendectin caused the injuries but this was deemed to be an improper conclusion based on "personal belief or opinion".

191 959 F 2d 1349 at 1353.

192 113 S Ct 2786 (1993) at 2792

193 *Ibid* at 2798.

194 *Daubert v Merrell Dow Pharmaceuticals Inc* 43 F 3d 1311 (9th Cir 1995)

195 *Ibid* at 1313-14

196 *Ibid* at 1317. It is useful to note that the notion that litigation motivated science should be of diminished status or inadmissible has itself proved to be flexible and difficult to apply in practical contexts For instance, such a strict rule would deny much forensic and a surprisingly wide variety of other scientific knowledges, a factor acknowledged by the court itself

to the processes of science: "[t]he ultimate test of [a scientific expert's] integrity is her readiness to publish and be damned."[197] Failure to follow the scientific method "as it is practiced by (at least) a recognized minority of scientists in their field" was seen as fatal to the plaintiff's expert testimony.[198] Their testimony was therefore deemed inadmissible. How these considerations were assessed remains unexplained.

F. From 'Authority' to 'Pathology': *Oxendine* as a Pyrrhic Victory

As late as November 1994, the final result of *Oxendine* remained to be determined. *Merrell Dow Pharmaceuticals Inc v Oxendine*[199] (*Oxendine IV*) was the fourth appeal in what was conservatively described as "extended litigation". By this stage Merrell was seeking to employ the outcome of earlier litigation, predominantly in its favour, in conjunction with 'further' evidence to effectively re-litigate its earlier trial loss. The judges recognised that there had been evidentiary changes over time and suggested that they "simply cannot use *Oxendine IV*... as a vehicle for second-guessing *Oxendine I*".[200] In a subtle concession, the judges revealed that finding the appropriate balance between the "need for closure" and the "opportunity to correct an injustice with newly-discovered evidence" was a difficult task:[201]

> The ends of the litigation process would be subverted if, as Merrell Dow seem to suggest, a jury's determination of a scientific fact after a full trial, twice affirmed by an appellate court, could by the subject of potentially endless re-examination except in the most unusual of circumstances.[202]

In deciding, they effectively limited Merrell's chances of success whilst accepting that there had been shifts in what was deemed to be 'acceptable' evidence over time which might influence any contemporary or future trial outcomes in favour of Merrell. But as for the appeal:

> considerations of finality have become so compelling that in my view, nothing short of an extraordinarily persuasive proffer by Merrell Dow would warrant new testimony, revisiting the jury's verdict and denying Ms Oxendine's recovery.[203]

VII. DISCUSSION

Out of this more detailed history a number of themes emerge. One of the most important observations that can be made is that much of the contest between plaintiffs and defendants involved attempts to ascribe epistemological authority to a number of concepts which had contested epistemic status. A number of scientific knowledge claims involved in the Bendectin litigation lacked 'natural'

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197 *Ibid* at 1318. Again Huber, note 4 *supra*, is used as authority for these claims
198 *Ibid* at 1319
199 649 A 2d 825 (DC App 1994).
200 *Ibid* at 834.
201 *Ibid* at 831
202 *Ibid* at 832
203 *Ibid* at 835

epistemological legitimacy. Attempts to grant such concepts epistemological legitimacy were seen by participants as preconditions for establishing their views. The processes operating display a number of similarities to those identified in scientific controversies by sociologists of science. Analysts such as Gilbert, Mulkay, Collins and Pinch have emphasised the use, by participants engaged in controversies, of discursive strategies involving the use of flexible interpretative repertoires.[204] When evaluating claims which they support, scientists tend to describe the justifications of such claims in terms of 'rational' constitutive processes such as methods, norms, absence of personal judgments and biases, and adequacy of community consensus and so on. Claims they oppose are actively deconstructed on the basis of social contingencies such as personal bias, interests, ambiguous evidence, unsound methodology and so on. One of the important points raised is that it is rare for there to be a clear discussion of how competing positions might rely on different epistemological models with different presuppositions, and there is little reflection on how one's own claims could possibly be exposed to potential sociological deconstruction.

In the Bendectin litigation, participants engaged in the construction/ deconstruction of the epistemological (scientific and legal) authority of a number of key domains. These include:

(i) The Appropriate Evidentiary Standards

Even a brief examination of the Bendectin litigation indicates a range of approaches and standards applied to the various types of knowledge 'available' throughout the litigation. Over the course of litigation there were differences in the stage at which courts decided that certain knowledge(s) were inadequate. The early cases of *Mekdeci* and *Oxendine* and the MDL demonstrate an openness, partly attributable to the lack of authority, to the types of science deemed acceptable in Bendectin trials. Thereafter, a range of judges and appellate courts arrived at less accommodating positions toward plaintiff evidence. These included finding the evidence admissible but insufficient to sustain a verdict; inadmissible as it was not properly scientific (under Federal Rules of Evidence 702, 703); and inadmissible and insufficient as a matter of law. The stage at which these decisions were made also varied. Judgments were given against plaintiffs summarily, notwithstanding a jury verdict in their favour, or directed verdicts when the jury was unable to reach agreement. Such variation problematises accounts advocating the availability of 'overwhelming' scientific evidence and also indicates how legal standards themselves exhibit a range of ambiguity and therefore discretion.[205]

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204 Mulkay, note 1 *supra*; Collins and Pinch, note 27 *supra*, N Gilbert and M Mulkay, *Opening Pandora's Box: A Sociological Analysis of Scientists' Discourse*, Cambridge University Press (1984).

205 D Galligan, *Discretionary Powers: A Legal Study of Official Discretion*, Oxford University Press (1990).

(ii) The Status, Authority and Credibility of Individual Scientists and Scientific Institutions

Throughout the various Bendectin trials and appeals there was disagreement over the status, authority and credibility of experts. Whilst the plaintiff expert Doctor Done had his testimony admitted in some early trials, Judge Wolf in the Superior Court of the District of Columbia considered some of his evidence from the *Oxendine* trial to be perjury. The finding of perjury was subsequently reversed in *Oxendine II*.[206] Without mentioning specific experts, the Ninth Circuit Court of Appeals in *Daubert* dismissed the approaches adopted by the plaintiffs' scientists. Considering the case on appeal, the Supreme Court described the same scientists as "well credentialed experts" and possessing "impressive credentials". The authority, credibility and methodologies of experts, which courts often combine, can be seen as flexible resources for use by both defendants and plaintiffs. The ability to deconstruct a scientist's science can be used to impugn their credibility, beyond just the instant case.[207] The plaintiffs and defendant were actively engaged in defending and vindicating their own scientists whilst attacking and discrediting the science of their opponents. Mass torts provide extensive resources and many opportunities to develop and refine both attacks and defences of experts, especially repeat players.[208]

One of the features of the Bendectin litigation was the asymmetry in the judicial assessment of experts. Experts for the plaintiff were more heavily scrutinised and apparently more suspicious than those provided by the defendant. This may be extended to the knowledge claims made by each. Examples include Rubin's reluctance during the MDL trial to investigate plaintiff assertions of bias in research undertaken on behalf of or in conjunction with Merrell, and the Ninth Circuit's unwillingness to ascribe scientific legitimacy to research undertaken in the 'shadow' of litigation. However, whether there is such clear distinction between the interests involved in the research of drug companies and the research undertaken for plaintiffs might be open to question. Indeed it would be naive to suggest that pharmaceutical corporations did not conduct their own research and prepare records with an 'eye' to potential litigation.

(iii) The Status, Authority and Credibility of Various Areas of Scientific Knowledge

We have already provided considerable evidence and discussion of the changing and negotiated status of various scientific knowledges across the Bendectin litigation. It is hoped that the extended case study would suggest that there was far more flexibility, discretion and uncertainty involved in determining appropriate legal approaches than has previously been expressed in other

206 *Merrell Dow Pharmaceuticals Inc v Oxendine* 593 A 2d 1023 (DC App 1991).

207 JA Schuster and RR Yeo, *The Politics and Method of Scientific Method*, Kluwer (1986)

208 Though he has approached the issue from a positivist framework, the development of approaches in scientific controversies into coherent positions, almost resembling ideologies, has been well documented by Mazur. A Mazur, *The Dynamics of Technological Controversy*, Communications Press (1981) For a commentary, see D Mercer, "Understanding Scientific/Technical Controversy", Science and Technology Policy Research Group, Occasional Paper No 1 (1996).

accounts. The eventual 'triumph' of epidemiology cannot be seen to represent a 'closed' position on the issue, adopted directly from the 'scientific community'. Tensions arise from competition *between* professional communities of scientists, such as toxicologists, pharmacologists and epidemiologists.[209] Further, these very communities are often fragmented. Courts often reach conclusions ('closure') concerning the appropriateness of the various types of evidence submitted by the different communities of scientists in ways that might not be defensible or comprehensible to those very communities, or at least significant parts of them. Indeed, there is an indication of 'widespread' disagreement over the appropriate role and standards for epidemiology.[210] In a brief submitted to the Supreme Court for the *Daubert* appeal, an eminent group of mainly Harvard trained epidemiologists challenged the Ninth Circuit's (and implicitly *Brock's*, before it) emphasis on 'statistical significance', reliance on peer-review and publication and rejection of re-analysis and meta-analysis. In turn that position was challenged by a brief in support of Merrell by one of the most prolific and eminent epidemiologists in the United States.[211]

The various scientific knowledges deployed in the Bendectin litigation came with no 'neutral' means of determining their appropriateness, comparative advantages and limitations. There were pre-existing positions on some of these issues, but these were themselves the subject of earlier professional negotiations, professional boundary management and conventions both in the scientific and legal communities.[212] For example, the Agent Orange litigation provided a resource for later courts to support their preference for epidemiological studies over animal studies. However, it did not 'determine' the manner in which epidemiology would be appropriated and championed in the various Bendectin cases.

(iv) The Status and Authority of Earlier Trials and Judgments

As the Bendectin litigation continued, the volume of resources on which courts considering the Bendectin cases could draw increased. The scale of the litigation and the huge sums involved meant that many of the cases were appealed, contributing to the available 'authority'. The use of earlier trials and

209 D Robbins and R Johnston, "The role of cognitive and occupational differentiation in scientific controversies" (1976) 6 *Social Studies of Science* 349

210 Brief *Amicus Curiae* of Professors Kenneth Rothman, Noel Weiss, James Robbins, Raymond Neutra and Steven Stellman in support of the Petitioners (*Daubert v Merrell Dow Pharmaceuticals Inc* note 194 *supra*. For some discussion of different approaches to epidemiology in law see. MM Thompson, "Causal Inference in Epidemiology Implications for Toxic Tort Litigation" (1992) 71 *North Carolina Law Review* 247; S Strawn and MS Legator, "Epidemiology and Toxic Torts: Animal Studies Yield Valid Insights" (1991) 27 *Trial* 61, O Wong, "Using Epidemiology to Determine Causation in Disease" (1988) 3 *Natural Resources & Environment* 20; G Taubes, "Epidemiology Faces its Limits" (1995) 269 *Science* 164, MG Farrell, "*Daubert v Merrell Dow Pharmaceuticals Inc*: Epidemiology and Legal Process" (1994) 15 *Cardozo Law Review* 2183; B Black and DE Lilienfield, "Epidemiologic Proof in Toxic Tort Litigation" (1984) 52 *Fordham Law Review* 732.

211 Brief *Amicus Curiae* of Professor Alvin R Feinstein in support of respondent (*Daubert v Merrell Dow Pharmaceuticals Inc* note 183 *supra*)

212 T Geiryn, "Boundary Work and Demarcation of Science from non-Science Strains and Interests in Professional Ideologies of Scientists" (1983) 48 *American Sociological Review* 781.

judgments enabled courts to rule on evidentiary issues without always requiring a detailed assessment of the evidence. The earlier trials proved to be very influential in the broader process of the Bendectin litigation. *Oxendine* was the most important of the trials for the plaintiffs whereas the MDL provided a trial administration and source of authority which favoured Merrell. Over time the appellate decisions became even more powerful sources of authority. Standards like those required by the appellate court in *Brock* meant that unless published epidemiological studies supporting the plaintiff emerged, there was to be no further litigation; no new evaluation of the 'evidence'. This is the case where the plaintiffs' evidence was excluded as 'a matter of law'. The tendency for courts to draw on each other and use similar types of legitimation for their decisions provides, superficially, the appearance that an epistemologically consolidated position, reflecting the concurrence of scientists, was emerging. That this impression has been accepted is in part a tribute to the power of certain institutions and their successful deployment of appropriate forms of rhetoric. Over time, the appearance of the supposed 'scientific consensus', constructed and approved by court after court, appears more and more compelling. However, 'authority' is not always determinative, and allows considerable interpretative discretion. The court in *Turpin* (also *DeLuca*), quite late in the litigation considered here, undertook their 'own' assessment of the issues because they believed that other courts had been too ready to rely purely on authority. The Sixth Circuit Court of Appeals expressed their belief that "courts have a duty to inspect the reasoning of qualified scientific experts".[213] The Sixth Circuit eventually produced a judgment that had the same effect as many of the earlier judgments, even if the reasoning was somewhat different.

(v) The Authority and Competence of Legal Institutions

Two examples of the authority of legal institutions are discussed below. First, the issue of legal authority is raised when appellate judges and trial judges reverse jury decisions or where appellate judges reverse the positions taken by trial judges. There are a number of cases where appellate courts reversed jury verdicts because they were supposedly based on insufficient or inadequate evidence (for example *Richardson* and *Brock*). In a sense this raises serious questions for the role of the jury, especially if considerations external to the instant trial such as consistency and rationing and even 'deterrence' enter and influence such reversals without explicit discussion. The second issue is raised by the failure of Bendectin to re-emerge on the market after mass litigation. Despite considerable support for its safety, the manufacturer promptly removed it from the market. If Bendectin was again produced for sale, it is not clear that American consumers would have faith in Merrell's 'legal vindication'.

(vi) Linkages to Broader Social Implications

The judges involved in the MDL and *Brock* supplemented their judgments with the introduction of social factors. They emphasised the importance of not

213 *Turpin v Merrell Dow Pharmaceuticals Inc* 959 F 2d 1349 (6th Cir 1992)

unduly fettering manufacturers through vexatious lawsuits concluding in inconsistent verdicts. They also emphasised the tremendous cost of mass litigation to the parties and the community. Both courts found in favour of the defendant, Merrell, on appeal. We do not suggest that there is some simple unmediated linkage between these factors, but such considerations appear to inform judicial decision-making. Whilst the impact of such litigation and decision-making on manufacturers might be a little more abstract, serious questions of legal representation and justice, largely unexamined (though acknowledged by Rubin and Weinstein)[214] are raised through forms of judicial economy and 'rationing'.[215]

VIII. CONCLUSION

The complex social negotiations involved in supplying meaning to these fluid categories highlight the weaknesses in providing synchronic reconstructions of complex mass tort litigation. Our examination of the Bendectin litigation suggests that similar studies of other mass toxic torts may well be important in helping to elucidate 'patterns' ('cycles') that would be impossible to observe through existing accounts. The existing accounts tend to rely on reconstructions of simplistic models of distortion of science and the objectives of the legal system as a by-product of social pressures and unethical behaviour. In the case of Bendectin, a 'rational' solution was seen to be available from the outset; that epidemiological evidence was authoritative and did not suggest any danger. This convenient reconstruction obscures the contingent and constructed nature of the 'closure' of Bendectin litigation. One might expect to find, in the future, that in other toxic tort cases epidemiology might not 'prevail' as the most authoritative science in knowledge 'closure'. Examples of the contingent nature of epidemiological authority in achieving knowledge closure in toxic torts can be observed in current debates around the status of epidemiology in assertions of harm caused by passive smoking and electric and magnetic fields (EMF).[216] In a number of legal and quasi-legal proceedings assessing the potential health risks associated with EMF, the authority of epidemiological studies has been deemed inferior to *in vivo*, and other studies. Whilst some accounts, such as Sanders', acknowledge that there may be stimulants to the scientific community's research into issues that are the subject of litigation, the ultimate power to achieve closure is seen to remain with the scientific community. Sanders' account never grapples with the existence of continuing dissent within such communities in relation to many of the issues subject to toxic tort litigation and fails to provide a more refined image of the ambiguity and blurring of boundaries between scientific research and legal knowledge in such contexts. Merely footnoting the

214 Rubin, notes 69, 70 *supra*. Weinstein refs: *In re Agent Orange Product Liability Litigation* 597 F Supp 740 (ED NY 1984) and *In re Agent Orange Product Liability Litigation* 611 F Supp 1221 (ED NY 1985).

215 Sanders, note 7 *supra* at 362-85.

216 Edmond and Mercer, note 58 *supra*

notion of 'trans-science' does not adequately address the complexities of establishing such boundaries. The type of analysis we have undertaken provides a rich image of how the ambiguities are an important site of contest. One of the difficulties with using the concept of trans-science to account for areas of scientific disagreement is the issue that it may well be arguable whether, and when, a question is scientific or 'trans-scientific'. If there was simple agreement on those matters which are trans-science then there would be no explanatory role for the concept. This makes the concept a contradictory catch-all to preserve simplistic positivist epistemologies of science in the face of 'contradictory evidence'.

It is simplistic to suggest that the scientific community can always be drawn on as an 'external' source to resolve 'authoritatively' the kinds of scientific issues brought before courts. Competing fields of science may be drawn upon to address the question before the court. The scientific knowledge constructed in legal contexts is deeply imbued with socio-legal considerations. For instance, it is artificial to imagine the existence and character of many bodies of scientific knowledge without legal and quasi-legal (regulatory) considerations (for example toxicology and forensic science).[217] Despite the contradictions involved in the appeal to the ideal of scientific authority divorced from litigation, such appeals are likely to persist as important rhetorical resources. It is difficult for courts to create decisions with authority based purely on legal (political) closure.[218] In a sense, there is a paradox facing courts. Whilst courts are relying on law-science knowledges (knowledges emanating from the specific contexts of law, science and society), these complexities remain hidden in the attempts to render 'legitimate' decisions. If the 'secret life of torts', that is, the complexity of negotiating tractable law-science knowledges, is acknowledged, it may be more difficult to legitimate legal decisions. But the revelation of political contingency (expediency) may well be preferable in the longer term for both courts and the public as under the weight of empirical evidence it becomes more difficult to maintain the myths that mass tort litigation is amenable to simple scientific solutions, located externally to the legal system.

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217 Smith and Wynne, note 60 *supra*, S Jasanoff, *The Fifth Branch. Science Advisers as Policymakers.* Harvard University Press (1990).

218 Y Ezrahi, "The Authority of Science in Politics" in A Thackray and E Mendelsohn (eds), *Science and Values: Patterns of Tradition and Change* (1974) p 215