ARTICLES

Daubert in the Lowlands

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INTRODUCTION

In June of 1993, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[1] a toxic tort case involving the alleged adverse health effects of the anti-nausea drug Bendectin. As the only medication ever approved by the United States Food and Drug Administration (FDA) for treatment of morning sickness,[2] Bendectin — manufactured by Merrell Dow — enjoyed considerable popularity among physicians. Between 1957 and 1982, physicians prescribed Bendectin to more than seventeen million pregnant women in the United States alone.[3]

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[1] 509 U.S. 579 (1993).

[2] *See* Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation*, *in* PHANTOM RISK, SCIENTIFIC INTERFERENCE AND THE LAW 101 (Kenneth R. Foster et al. eds., 1993).

[3] *See* Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1313 (9th Cir. 1995). The

Twenty years after the drug entered the U.S. market, the first Bendectin suit, *Mekdeci*, was filed, alleging that the drug caused limb reduction birth defects.[4] *Mekdeci* was followed by about 1700 suits filed against Merrell Dow,[5] which caused the company to voluntarily withdraw Bendectin from the market in 1983. These suits resulted in more than twenty-seven trials in the United States. In most of these trials, Merrell Dow won jury verdicts.[6] Several other suits resulted in summary judgments for Merrell Dow.[7] Among the reasons courts frequently cited for granting the motions for summary judgment was the lack of epidemiological evidence that Bendectin is a teratogen.[8]

The suit filed by William Daubert and Eric Schuller and their respective guardians shared the fate of those cases. In 1989, the United States District Court held that the plaintiffs could not meet their burden of proving that Bendectin caused the birth defects at issue, and granted Merrell Dow's motion for summary judgment.[9] The United States Court of Appeals for the Ninth Circuit affirmed this decision on appeal. Referring to decisions of four other circuits, the Ninth Circuit held that the animal and chemical studies proffered by the plaintiffs were insufficient to establish a causal link between Bendectin and the plaintiffs' birth defects. The court further ruled that the reanalyses of

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drug was sold in 22 countries before the manufacturer withdrew it. Worldwide, more than 33 million women are reported to have used the drug. Lasagna & Shulman, *supra* note 2, at 138.

[4] Mekdeci v. Merrell Nat'l Lab., 711 F.2d 1510, 1512 (11th Cir. 1983). The federal district judge awarded the parents of David Mekdeci, born with a malformed arm and caved-in chest, $20,000 for medical expenses. *See id.* Merrell then filed a motion for a new trial, asserting that it was logically inconsistent to compensate the parents for medical expenses but not to award damages to the injured child. *See id.* The court granted the motion for a new trial. *See id.* at 1513. This new trial ended in victory for Merrell, a decision the Court of Appeals for the 11th Circuit subsequently upheld on appeal. *See id.* at 1513, 1524.

[5] *See* Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 4 (1993). More than 1100 complaints were consolidated in *In re Richardson-Merrell, Inc. "Bendectin" Prod. Liab. Litig.*, 624 F. Supp. 1212, 1216 n.1 (S.D. Ohio 1985), *aff'd* 857 F.2d 290 (6th Cir. 1988), *cert. denied sub nom.* Hoffman v. Merell Dow Pharms., 488 U.S. 1006 (1989).

[6] *See* Sanders, *supra* note 5, at 4-5.

[7] *See id.* at 11. In note 35, Sanders cites 18 Bendectin cases that resulted in summary judgment for the defendant. *See id.* at 11 n.35.

[8] *See id.* at 11-12. A teratogen is a substance that causes birth defects. Lasagna & Shulman, *supra* note 2, at 28. A carcinogen is a substance that causes cancer. *Id.*

[9] *See* Daubert v. Merrell Dow Pharms., Inc., 727 F. Supp. 570, 571 (S.D. Cal. 1989).

epidemiological studies proffered by the plaintiffs were inadmissible, because this type of evidence was not generally accepted by the scientific community.

In a long awaited decision, the United States Supreme Court reversed the Ninth Circuit's ruling.[10] The Court held that the "general acceptance" test for the admissibility of novel scientific expert evidence,[11] employed by the Ninth Circuit in *Daubert* in assessing the epidemiological studies, should no longer be used in federal trials.[12] Instead, the Court stated, courts should employ Federal Rule of Evidence 702,[13] and ensure "that any and all scientific testimony or evidence admitted is not only relevant, but *reliable*."[14] This standard of evidentiary reliability requires that the expert's testimony pertain to scientific knowledge that will assist the trier of fact in determining the issues. Scientific knowledge, the Court stated, is knowledge arrived at by the scientific method.[15] Whether it constitutes such depends on factors such as testability, known or potential rate of error, peer review, and general acceptance by the scientific community.[16] In other words, the fact that a method has been generally accepted may not in and of itself suffice to render the evidence

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[10] *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 598 (1993).

[11] This "general acceptance" standard was first articulated by the U.S. Court of Appeals for the District of Columbia in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923). Presented with the question of whether the systolic blood pressure test — a forerunner of the polygraph — was admissible in court, the court argued that

> [j]ust when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. at 1014.

[12] *See Daubert*, 509 U.S. at 587.

[13] Federal Rule of Evidence 702 reads as follows: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." FED. R. EVID. 702.

[14] *Daubert*, 509 U.S. at 589 (emphasis added).

[15] *See id.* at 590. "Scientific," according the U.S. Supreme Court, means "ground[ed] in the methods and procedures of science." Knowledge, according to the Court, means "more than a subjective belief or unsupported speculation." *Id.*

[16] *See id.* at 593-94.

admissible. Likewise, the fact that the method used has not been generally accepted — as appears to be the case with respect to epidemiological studies — does not mean the evidence is therefore inadmissible. Other factors, for example whether the technique has since been tested and subjected to peer review, may cause judges to conclude that the evidence does constitute scientific knowledge under Rule 702, and should therefore be admitted.[17]

The Supreme Court's turns in *Daubert* proved quite sensational and, in the three years that have since passed, many commentators have taken issue with the decision and its evidentiary and procedural consequences for (mass toxic) tort litigation. Most of these commentators have equated *Daubert* with some form of progress.[18] Others, however, have argued that the test the Supreme Court set forth is too ambiguous,[19] indeterminative,[20]

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[17] *See generally* G. Michael Fenner, *The* Daubert *Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 CREIGHTON L. REV. 939, 953 (1996) (arguing that dilemma of *Daubert* is that it is both more and less restrictive on admission of expert evidence).

[18] *See* Bert Black, *The Supreme Court's View of Science: Has* Daubert *Exorcised the Certainty Demon?*, 15 CARDOZO L. REV. 2129, 2137 (1994) (applauding court for recognizing contingent nature of science); Bert Black et al., *Science and the Law in the Wake of* Daubert*: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 721 (1994) (arguing that *Daubert* points in right direction, and that properly applied, it should mean deeper and more detailed preliminary review of scientific claims); Kenneth J. Chesebro, *Taking* Daubert*'s "Focus" Seriously: The Methodology/Conclusion Distinction*, 15 CARDOZO L. REV. 1745, 1753 (1994) (arguing that decision establishes clear and rigorous framework for analysis); Samuel R. Gross, *Substance and Form in Scientific Evidence: What* Daubert *Didn't Do*, 3 SHEPARD'S EXPERT & SCI. EVID. Q. 129, 130 (1995) (arguing that "the good news about *Daubert* is that the Supreme Court got it right"); Edward J. Imwinkelried, *The* Daubert *Decision on the Admissibility of Scientific Evidence: The Supreme Court Chooses the Right Piece for All the Evidentiary Puzzles*, 9 ST. JOHN'S J. LEGAL COMMENT. 5, 13 (1993) (contending that *Daubert* was practical solution and vindicated Federal Rules as coherent evidence code); Marc S. Klein, *After* Daubert*: Going Forward with Lessons From the Past*, 15 CARDOZO L. REV. 2219, 2222 (1994) (presenting possible solutions for judge's new role as gatekeeper of scientific evidence); Michael J. Saks, *Implications of the* Daubert *Test for Forensic Identification Science*, 1 SHEPARD'S EXPERT & SCI. EVID. Q. 427, 434 (1994) (arguing that *Daubert* test offers first real promise of serious scrutiny); Robert Simon, *Some Answers to the* Daubert *Puzzle*, 9 ST. JOHN'S J. LEGAL COMMENT. 37, 39 (1993) (arguing that *Daubert* is "major advance in the jurisprudence of law and science").

[19] *See, e.g.*, Richard D. Friedman, *The Death and Transfiguration of* Frye, 34 JURIMETRICS J. 133, 141-43 (1994) (discussing ambiguity in *Daubert*'s scientific admissibility criteria); Paul S. Milich, *Controversial Science in the Courtroom:* Daubert *and the Law's Hubris*, 43 EMORY L.J. 913, 926 (1994) (arguing that *Daubert* sets forth vague standard for handling science in courtroom).

[20] *See, e.g.*, Randolph N. Jonakait, *The Meaning of* Daubert *and What that Means for Foren-*

too complicated for federal judges to apply,[21] downright wrong on the interface between law and science,[22] or at odds with Congress's intentions when it passed the Federal Rules of Evidence.[23]

It goes without saying that the United States is not the only country facing mass toxic tort cases and the peculiar problems that arise in that context. Yet, both the American legal system's involvement with these cases and its struggle to stop the flood of unreliable scientific expert evidence,[24] a struggle of which *Daubert* is representative, seems to have few parallels in the western world. Part of this western world — most of the European mainland — does not employ standards for the admissibility of

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sic Science, 15 CARDOZO L. REV. 2103, 2104 (1994) (arguing that "[t]he opinion fails to provide meaningful guidance on how to follow the path; no firm method for making the determination was given"); Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts after* Daubert, 78 MINN. L. REV. 1387, 1391 (1994) (suggesting that Court failed to offer clear guidelines for admitting scientific evidence).

[21] *See Daubert*, 509 U.S. at 598 (Rehnquist, C.J., dissenting). This criticism was first articulated by Chief Justice Rehnquist in *Daubert* itself. *See id.* Although the Chief Justice in his dissenting opinion stated that the Court correctly concluded that *Frye* did not survive the Federal Rules of Evidence, he argued that questions arise from simply reading the Court's arguments on scientific knowledge "and countless more questions will surely arise when hundreds of district judges try to apply its teaching to particular offers of expert testimony." *See id.* at 600 (Rehnquist, C.J., dissenting); *see also* Paul C. Giannelli, Daubert*: Interpreting the Federal Rules of Evidence*, 15 CARDOZO L. REV. 1999, 2022-25 (1994) (discussing two federal voiceprint cases that had difficulty applying *Daubert*'s reliability approach); Barry C. Scheck, *DNA and* Daubert, 15 CARDOZO L. REV. 1959, 1961 (1994) (expressing fear that in era of overcrowded dockets, *Daubert* test may degenerate into "a rigid,... four-factor exercise in labeling"); *Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1515 (1995) [hereinafter *New Challenges*] (arguing that many courts have not followed admonition that factors enlisted in *Daubert* constitute general observations rather than definitive checklist).

[22] *See, e.g.*, Rochelle Cooper Dreyfus, *Is Science a Special Case? The Admissibility of Scientific Evidence After* Daubert v. Merrell Dow, 73 TEX. L. REV. 1779, 1788-1800 (1995) (arguing that Supreme Court was wrong to treat science as special case); Margaret G. Farrell, Daubert v. Merrell Dow Pharmaceuticals Inc.*: Epistemiology and Legal Process*, 15 CARDOZO L. REV. 2183, 2185 (1994) (arguing that decision exemplifies "law's failure to recognize and take into account changing conceptions of science and its ability to comprehend the world"). *But see* Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 2 (1995) (arguing that Court's approach reflects scientists' own approach to deciding which information to consider).

[23] *See, e.g.*, Leslie A. Lunney, *Protecting Juries From Themselves: Restricting the Admission of Expert Testimony in Toxic Tort Cases*, 48 SMU L. REV. 103, 185 (1994) (stating that courts have restricted admissible testimony inconsistently with Federal Rules).

[24] *See* David L. Faigman, Commentary, *A Response to Professor Carlson: Struggling to Stop the Flood of Unreliable Expert Testimony*, 76 MINN. L. REV. 877, 877 (1992).

scientific expert evidence at all. This does not mean, however, that the rationales underlying admissibility rules as such are unknown to European systems of law. Control and regulation of the proof process usually take place by rules pertaining to assessment and evaluation of evidence. The Continental equivalent of admissibility rules could best be described as decision and argumentation rules, not rules limiting what evidence the parties can present to the trier of fact, or how they need to do so.[25]

The question central to this contribution is how Continental systems of law approach the substantive issue with which *Daubert* dealt: the issue of liability in toxic tort cases. This Article also considers the related issue of proving causation in such a case. Specifically, how do these systems deal with the problems caused by the uncertainty that surrounds many alleged toxic substances? In this Article, we discuss these questions in relation to Dutch civil law. Part I is devoted to the difficulty of proving causation in mass toxic tort cases. In Part II, we focus on the *Daubert* case. Part III provides a general sketch of the Dutch law of evidence. Part IV deals with asbestos ligation in the Netherlands, while Part V discusses two decisions of the Dutch Court of Cassation (Supreme Court) regarding the drugs Halcion and DES. In Part VI, we examine the use of expert evidence in such cases. Part VII concludes our analysis, while in Part VIII we return to *Daubert* by speculating about the outcome of the case had it been situated in the Lowlands.

I. PROVING CAUSATION IN MASS TOXIC TORT CASES

In all toxic tort cases, the issue of causation is central to the legal dispute. Not only must the plaintiff establish that there is a statistically significant correlation between a particular product and certain harmful effects (general causation), the plaintiff

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[25] Methodologically seen, investigation and fact-finding can be divided in three stages with a different function: (1) the context of discovery (gathering of data); (2) the context of pursuit (testing hypotheses); and (3) the context of justification (argumentation in order to motivate decision). By and large, Anglo-American rules of evidence as rules of presentation pertain directly to (2), whereas Continental rules of evidence mainly affect (3), and only indirectly affect (2). *See* J.F. Nijboer, STRAFRECHTELIJK BEWIJSRECHT 57-59 (3d ed. 1997); J.F. Nijboer, *Common Law Tradition in Evidence Scholarship Observed From a Continental Perspective*, 41 AM. J. COMP. L. 299, 312-19 (1993).

must also establish that it is more likely than not that the product caused the harmful effects in this particular case (special causation). Causation is the most difficult, and sometimes nearest to impossible, thing for the victims of alleged toxic agents to prove, even under the "preponderance of evidence" standard, and ignorant of legal contexts.[26] As long as the substance at issue produces what is known as a signature disease — a disease uniquely linked to a particular product[27] — it may be less problematic to prove causation. The presence of the disease, together with a showing that the victim has been exposed to the substance in the past, proves causation by a preponderance of evidence. However, plaintiffs still must show that there are no confounding factors — other possible causes of the disease suffered by the plaintiffs[28] — and that the particular defendant is in fact liable for producing, distributing, or not having protected plaintiff against the substance.

Many alleged toxic substances, however, do not produce signature diseases, nor do they have obvious or clearly harmful effects.[29] Among the most well known of these types of substanc-

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[26] *See, e.g.*, Brechje Van der Velden, *Causaliteit onder hoogspanning. Een fictieve claim raakt de grenzen van het civiele aansprakelijkheidsrecht*, final paper Leiden University — June 1996. In this paper, the author analyzes what for Holland is still a fictitious claim (the claim that plaintiff's damage has been caused by exposure to electromagnetic fields) according to the principles of Dutch tort law (paper on file with authors).

[27] *See* Sheila Jasanoff, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 119 (1995); Sanders, *supra* note 5, at 13. Mesothelioma, for example, is a very rare disease, "except in individuals exposed to asbestos," and is "strongly associated with asbestos exposure." Ralph D'Agostino, Jr. & Richard Wilson, *Asbestos: The Hazard, the Risk, and Public Policy*, *in* PHANTOM RISK, SCIENTIFIC INTERFERENCE AND THE LAW 193 (Kenneth R. Foster et al. eds., 1993). Other diseases associated with asbestos, such as bronchial carcinoma, may also result from other substances, such as cigarettes. *See id.* at 196. DES is known to cause particular forms of vaginal cancer "that otherwise occurs extremely infrequently in the general population." Jasanoff, *supra*, at 119.

[28] *See, e.g.*, Jasanoff, *supra* note 27, at 120 (stating that "even asbestos victims cannot always demonstrate that conditions other than mesothelioma — specifically, lung cancer and damage to lung tissue — were caused by exposure to asbestos rather than by other causes such as smoking").

[29] *See* Sanders, *supra* note 5, at 13-14. This may be extremely difficult: many alleged toxic substances have an unknown or a limited number of manufacturers, which may make it extremely difficult for plaintiffs to uniquely identify the defendant responsible for manufacturing or distributing the particular drug. In the Bendectin litigation, this problem did not surface because the drug was manufactured by one particular company. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 582 (1993). Drugs such as DES, however, were not patented and were manufactured by many different pharmaceutical companies or phar-

es, at least in the United States, are Bendectin, Electromagnetic Fields (EMFs),[30] Halcion, and silicone gel breast implants.[31] As one commentator has noted:

> All of these substances or forces share three defining characteristics: They do not produce a signature disease; there is no generally accepted biological theory about how they produce their alleged effect; and there is only a weak correlation between the substances or force and the injury.[32]

In other words, it is scientifically uncertain whether or not these agents are toxic substances or not, and the uncertainty is even greater in individual cases. In the midst of this scientific uncertainty, courts are faced with lawsuits filed against the alleged manufacturers of these substances, and diametrically opposed experts. Ultimately, these courts have no other option but to decide the case. In criminal cases, doubt tends to favor the defendant, keeping in mind that *in dubio pro reo*.[33] Yet, that option seems far less attractive in toxic tort cases. By their very

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macies. In the U.S., this problem was solved by determining that a plaintiff who could not uniquely identify the manufacturer responsible for producing DES could proceed against a group of pharmaceutical companies that together represented most of the market. Should the plaintiff be able to prove causation, each defendant would be liable for the size of its market share, unless it can prove that it did not produce or distribute the drug that caused the injury. *See* Sindell v. Abbott Lab., 607 P.2d 924, 933 (Cal. 1980) (analyzing enterprise liability theory and application in DES case). In the Netherlands, the Dutch Court of Cassation took the argument one step further in *DES-dochters/Bayer c.s.*, HR 9 October 1992, NJ 1994, 535. *See infra* notes 137-51 and accompanying text (discussing holding in *DES-Dochters* case).

[30] *See, e.g.*, Kristopher D. Brown, Note, *Electromagnetic Field Injury Claims: Judicial Reaction to an Emerging Public-Health Issue*, 72 B.U. L. REV. 325, 338-39 (1992) (discussing difficulties plaintiffs face when proving causation in EMF cases); Todd D. Brown, Comment, *The Power Line Plaintiff & The Inverse Condemnation Alternative*, 19 B.C. ENVTL. AFF. L. REV. 655, 657 (1992) (discussing that plaintiffs exposed to EMF may be unable to recover because scientists have not yet proven causal link between EMF exposure and health effects); C. Michelle Depew, Comment, *Challenging the Fields: The Case for Electromagnetic Field Injury Tort Remedies Against Utilities*, 56 U. PITT. L. REV. 441, 443-44, 449-82 (1994) (same); Roland A. Giroux, Note, Daubert v. Merrell Dow: *Is This Just What the EMF Doctor Ordered?*, 12 PACE ENVTL. L. REV. 393, 433 (1994) (same); James H. Stilwell, Note, *Straddling the Wire: Electromagnetic Fields and Personal Injury Suits*, 14 REV. LITIG. 545, 576 (1995) (same); Margo R. Stoffel, Comment, *Electromagnetic Fields and Cancer: A Legitimate Cause of Action or a Result of Media-Influenced Fear?*, 21 OHIO N.U. L. REV. 551, 563-79, 583 (1994) (same); Christopher A. Wilson, Comment, *Power Line EMF: A Proposed State Utility Regulatory Response*, 10 J. CONTEMP. HEALTH L. & POL'Y 469, 475 (1994) (same).

[31] *See* Feldman, *supra* note 22, at 18-25 (giving overview of breast implant litigation).

[32] Sanders, *supra* note 5, at 13.

[33] "Doubt benefits the defendant."

nature, toxic substances have the potential to affect large groups of people, and so does the litigation that centers around these substances. For example, if it is ever scientifically proven to be a teratogen,[34] the manufacturers of Bendectin will be liable for the detrimental effects the drug had on the lives of millions of babies, considering that it was administered to more than 17.5 million women over a period of twenty-five years. If EMFs are ever proved to cause, or further, cancer, their producers may similarly be liable to millions. Moreover, should these substances become qualified as toxic agents, the effect might be felt for generations; both DES and asbestos are now working their way through a second generation of victims.

In this environment, adjudicating tort cases is not finding the facts, because there is little fact to find. Rather, it is attempting to decide "who should bear the costs of society's inability to ascertain the relevant facts with any degree of certainty."[35]

II. THE BENDECTIN LITIGATION: *DAUBERT V. MERRELL DOW PHARMACEUTICALS, INC.*[36]

Daubert was not the first Bendectin case to reach the courts, nor was it exceptional in its circumstances or the result reached. In each and every Bendectin case, plaintiffs argued that the limb reduction birth defects they suffered were due to Bendectin consumption by their mothers during pregnancy. In order to prove causation, the plaintiffs in *Daubert*, like most Bendectin plaintiffs, proffered expert evidence based on *in vivo* and *in vitro* animal studies, chemical structure analyses and a reanalysis of epidemiological studies conducted in the past. Like most other Bendectin plaintiffs, they lost their case. The district court held that the plaintiffs could not meet their burden of proving causation, and granted summary judgment to the defendant Merrell

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[34] In light of the available scientific data, most commentators consider it unlikely that Bendectin is a powerful cause of birth defects, although this data cannot rule out the possibility that it might "cause undetectable small increases in the rate of birth defects." *See* Lasagna & Shulman, *supra* note 2, at 109. To prove that Bendectin, or any other suspected agent is *not* a toxic agent is logically impossible. This is one reason why claims that they might constitute toxins are likely to resurface time and time again. *See* Sanders, *supra* note 5, at 27 (arguing that "a definitive case exonerating Bendectin . . . cannot be made").

[35] Jasanoff, *supra* note 27, at 123.

[36] 509 U.S. 579 (1993).

Dow.[37] The Court of Appeals for the Ninth Circuit affirmed.[38] With reference to the decisions of four sister circuit courts in Bendectin cases,[39] the Ninth Circuit held that the animal and chemical studies failed because they were insufficient to establish a causal link between Bendectin consumption and the injuries of which the plaintiffs complained. In addition, the required epidemiological studies proffered by the plaintiffs failed to pass muster, because they did not satisfy the *Frye* general acceptance test[40] for the admissibility of novel scientific evidence.[41] Given the insufficient foundation of plaintiffs' argument, they could not satisfy their burden of proving causation.[42]

In light of the Supreme Court's subsequent decision in the case, the use of the general acceptance test by the District and Circuit courts was a mistake. The Supreme Court held that the test had since been supplanted by the Federal Rules of Evidence, and should no longer be used in federal trials.[43] But the use of *Frye* in this particular tort case was also quite significant. Although the notion that novel scientific expert evidence needs to be generally accepted in the scientific community developed into the almost universal view of American courts in criminal matters,[44] it was rarely used in civil cases.[45]

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[37] For an overview of all Bendectin cases with which the American courts have dealt up to 1993, see Sanders, *supra* note 5, at 4-12.

[38] *See* Daubert v. Merrell Dow Pharms., Inc., 951 F.2d 1128, 1131 (9th Cir. 1991).

[39] The Ninth Circuit referred to *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941 (3d Cir. 1990); *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988); *Lynch v. Merrell-Nat'l Labs.*, 830 F.2d 1190 (1st Cir. 1987). *See Daubert*, 951 F.2d at 1130.

[40] *See* Frye v. United States, 293 F. 1013, 1013 (D.C. Cir. 1923) (discussing contours of general acceptance test for scientific evidence).

[41] *See Daubert*, 951 F.2d at 1131. The Court argued that plaintiffs' reanalysis did not comply with the requirements that it be subjected to verification and scrutiny by others in the field. *See id.*

[42] *See id.*

[43] *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 585-89 (1993) (analyzing legislative history and concluding that Federal Rules of Evidence displaced *Frye* standard).

[44] *See* Edward J. Imwinkelried, *The Standard for Admitting Scientific Evidence: A Critique from the Perspective of Juror Psychology*, 28 VILL. L. REV. 554, 556-57 & n.19 (1982-83) (discussing courts' widespread application of general acceptance test and listing representative cases); Andre A. Moenssens, *Admissibility of Scientific Evidence — An Alternative to the* Frye *Rule*, 25 WM. & MARY L. REV. 545, 546 (noting that since late 1960s, courts have cited *Frye* in virtually every criminal prosecution dealing with novel form of expert evidence).

[45] In an en banc ruling, the Court of Appeals for the Fifth Circuit applied *Frye* to a civil case in *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1110-12, 1115-16 (5th Cir. 1991)

By the time *Daubert* reached the courts, however, they had become besieged with criticism regarding their use of scientific evidence, particularly in tort cases.[46] Critics argued that courts do not adequately comprehend complex scientific information, and allow for too much unreliable expert testimony — "junk science" — to reach the trier of fact.[47] These arguments sparked a debate over what was to be considered the most serious of problems, as well as a movement to take hold of expert evidence.[48] It was against the background of this debate about junk science that the Ninth Circuit approved the District Court's use of the stringent *Frye* standard in *Daubert*,[49] despite the fact that the *Frye* standard seemed to be at odds with the standard for admissibility provided by Federal Rule of Evidence 702.

Although the Supreme Court's decision in *Daubert* appears to be motivated by the same desire to reign-in expert evidence, the Supreme Court declined to adopt the *Frye* test.[50] Instead, it

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(en banc) (per curiam). The court followed the decision in a 1984 case, in which a panel of judges held *Frye* applicable in civil matters. *See generally Recent Case — Evidence — Admissibility of Scientific Evidence — Fifth Circuit Limits Permissible Scientific Evidence to Generally Accepted Theories* — Christophersen v. Allied Signal Corp., *939 F.2d 1106 (5th Cir. 1991) (en banc) (per curiam)*, 105 HARV. L. REV. 791 (1992). In other words, *Daubert* was apparently only the third federal civil case in which *Frye* was used. *See* Gross, *supra* note 18, at 140.

[46] *See, e.g.*, Jasanoff, *supra* note 27, at 114 (arguing that "courts have rarely drawn as much fire for their supposed misuse of scientific information as in adjudication toxic tort claims").

[47] Peter W. Huber is one of the best-known authors sparking the debate on the system's perceived flaws in relation to expert evidence. His book, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991), is widely known for its telling examples of junk science in American courtrooms. In Chapter Seven, *Nausea: The Massed Legal Attack*, Huber recounts the tale of the Bendectin cases. The real Bendectin disaster, Huber argues, is that because Bendectin disappeared from the medical market, there is no drug available to counter the severe effects of morning sickness. *Id.* at 128-29. The "significant therapeutic gap" — as the American College of Obstetrics and Gynecology called it — that resulted from that decision may in turn lead to an increase in birth defects. *Id.* at 129.

[48] For more interesting analyses on the nature of the problem and a suggestion of remedies for some of these problems, see Margaret A. Berger, *Procedural and Evidentiary Mechanisms for Dealing with Experts in Toxic Tort Litigation: A Critique and Proposal*, A CONSULTANT REPORT FOR THE CARNEGIE COMMISSION'S TASK FORCE ON SCIENCE AND TECHNOLOGY IN JUDICIAL AND REGULATORY DECISION MAKING (Oct. 1991); Faigman, *supra* note 24, at 877.

[49] The Court of Appeals explicitly cited Huber's attack on the law's approach to junk science, stating that "the best test of certainty we have is good science — the science of publication, replication, and verification, the science of consensus and peer review." Daubert v. Merrell Dow Pharms., Inc., 951 F.2d 1128, 1131 (9th Cir. 1991) (quoting Huber); *see also* HUBER, *supra* note 47, at 228.

[50] *Daubert*, 509 U.S. at 596. Faced with Merrell Dow's concern that abandonment of the

urged federal courts to serve as gatekeepers. From that time on, the courtroom door was to be closed to scientific evidence not grounded in the methods and procedures of science.[51] The focus was to be solely on principles and methodology, "not on the conclusions they generate."[52]

Whatever changes the Supreme Court made in relation to the admissibility of scientific expert evidence, it neither mitigated the uncertainty so characteristic of mass toxic tort cases,[53] nor did it alter the Ninth Circuit's decision that the plaintiffs were to carry the burden of that uncertainty. On remand, the Ninth Circuit again affirmed the District Court's decision to grant summary judgment to the defendant, while expressing serious doubts about the wisdom of the Supreme Court's arguments.[54] If anything, it appeared to strengthen the Ninth Circuit's belief that its original decision to find against the plaintiffs was correct.

In its first opinion, the Ninth Circuit had argued that "the reanalysis of epidemiological studies is generally accepted by the scientific community *only* when it is subjected to verification and scrutiny by others in the field."[55] Given that the Supreme Court mentioned both these elements as factors bearing on the question of the reliability of scientific evidence,[56] one may have ex-

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general acceptance test would result in a "free-for-all" in which juries would be confounded by "absurd and irrational pseudoscientific assertions," the court noted that respondent was "overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.*

[51] *See id.* at 589 (describing trial judge's screening ability).

[52] *See id.* at 595; *see also* Chesebro, *supra* note 18, at 1746 (observing that Rule 702 authorizes courts to focus on scientific validity of evidence, not on conclusions).

[53] Or, as Feldman has argued, *Daubert* will result in reasonable factfinders being "left in a state of strong uncertainty about general causation, unable to conclude that it is more likely than not that a litigated substance is safe, or that it is more likely than not that the substance is unsafe." Feldman, *supra* note 22, at 2.

[54] Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1322 (9th Cir. 1995). Under the heading "Brave New World," the Ninth Circuit argued that the first prong of *Daubert* (determining whether expert testimony constitutes scientific knowledge) "puts federal judges in an uncomfortable position." *Id.* at 1315. The court went on to state that "[t]he task before us is more daunting still when the dispute concerns matter at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability." *Id.*

[55] Daubert v. Merrell Dow Pharms., Inc., 951 F.2d at 1131 (emphasis added).

[56] *See Daubert*, 509 U.S. at 593 (noting that scientific methodology requires testing to

pected the Court of Appeals to simply restate, augment, and affirm the Supreme Court's holding. The court did indeed restate the importance of verification and peer review, but not specifically in relation to the epidemiological studies. Instead, the court argued that because none of the plaintiffs' experts based his testimony on preexisting or independent research — a factor not mentioned by the Supreme Court, but nevertheless found crucial by the appellate court — plaintiffs had to produce "other objective, verifiable evidence that the testimony was based on scientifically valid principles."[57] Even though Bendectin litigation had been pending in the courts for over ten years, review or publication of the experts' work was absent.[58]

Notwithstanding the absence of review or publication, the Ninth Circuit held that plaintiffs may offer the testimony of their own experts on the methodology they used to satisfy the plaintiff's burden of showing that the evidence was derived by the scientific method.[59] The court then stated that if methodology had been the only issue it needed to consider, it would have been inclined to remand to the district court, so as to "give the plaintiffs an opportunity to submit additional proof"[60] of the reliability of the experts' testimony. But the Ninth Circuit was not prepared to remand in *Daubert*. With the exception of one expert, the only thing to which the plaintiffs' experts were willing to testify was that Bendectin was *capable* of causing birth defects. The Ninth Circuit considered this testimony unhelpful to the trier of fact in determining whether Bendectin *did* cause the birth defects suffered by these plaintiffs. The court therefore ruled the testimony inadmissible under FRE 702. The inadmissibility of the experts' testimony again resulted in the plaintiffs' failure to prevail on the issue of causation. Thus, the District Court's summary judgment was affirmed.[61]

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determine whether results can be falsified).

[57] *Daubert*, 43 F.3d at 1317-18.

[58] *See id.* (noting that none of plaintiffs' experts published work in scientific journals or solicited formal reviews by colleagues).

[59] *See id.* at 1319 (describing one approach to admit evidence without publication is to prove result of scientific methodology).

[60] *Id.* at 1320.

[61] *See id.* at 1322.

If the Ninth Circuit's analysis on remand is correct or justifiable under the Supreme Court's analysis in *Daubert*,[62] and is an example of what is yet to come, then *Daubert* seems to have considerable anti-plaintiff potential.[63] In many toxic tort cases, studies are frequently conducted in connection with litigation, and not before it. Indeed, as Jasanoff has argued, "to satisfy the civil law's 'preponderance of the evidence' (or more likely than not) test, what is 'known' about a chemical from the general scientific literature almost always has to be supplemented by knowledge acquired about particular individuals and communities of claimants."[64] Although having been prepared for litigation does not make the evidence inadmissible, it does make it far more difficult to get the evidence admitted under the Ninth Circuit's analysis.

More problematic, perhaps, is the Ninth Circuit's holding that expert testimony to the effect that Bendectin might be capable of causing birth defects is inadmissible, because it would not assist the trier of fact in determining the issues. Although that interpretation may be considered justified under *Daubert*, in light of the required "fit" between testimony and issues to be determined, it has been argued that it is almost certainly wrong in light of the intentions of Congress regarding the Rules upon which *Daubert* relied.[65] Moreover, although the court says the evidence is inadmissible, what the court in fact argues is that it is insufficient.

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[62] *See* Fenner, *supra* note 17, at 989-91. *But see New Challenges*, *supra* note 21, at 1516 (arguing that decision of appellate court on remand seems to completely disregard "the Court's admonition to inquire into the scientific principles and methodology of the proposed testimony").

[63] Indeed, Gross has argued that at least "the first batch of federal cases applying *Daubert*" are consistent with the prediction that *Daubert*'s main effect would be the exclusion of more purportedly scientific evidence than they would have under the original *Frye* test. *See* Gross, *supra* note 18, at 145 n.82.

[64] Jasanoff, *supra* note 27, at 119; *see also* Sanders, *supra* note 20, at 1423 (arguing that "the problem with Dr. Swan's testimony [Dr. Swan testified in many Bendectin cases, including *Daubert*] arose because she completed the reanalysis for the purpose of litigation; she was not testing a research hypothesis. To exclude her testimony on this ground, however, would condemn many, if not most reanalysis of existing data by experts hired for litigation.").

[65] *See* Lunney, *supra* note 23, at 151-56 (discussing congressional intent in Federal Rule of Evidence 702 to assist trier of fact).

In one respect, there is little difference between a decision holding the evidence insufficient and one holding the evidence inadmissible. Both foster judicial efficiency and reduce the probability that the jury will fail to pierce the mystic infallibility that surrounds scientific expert claims, or so one could argue.[66] But in another respect, there is quite some difference. Whether evidence is inadmissible is a question of law that the judge is perfectly allowed — although perhaps not always perfectly able — to answer. Although the same is true for a question of legal sufficiency, as Gross argues, a decision on legal sufficiency "looks and sounds like a judgment on the weight of the evidence — it *is* a judgment on the weight of the evidence, only an extreme one."[67] Thus, courts seem to "go to unfortunate lengths to find that essential parts are inadmissible, and then say that there's not enough left to go to the jury."[68] As Gross further argues, "this is particularly true for expert evidence, since traditionally courts have held that the testimony of any qualified expert is sufficient to sustain a verdict on any issue on which she testified."[69]

To be sure, that trend — first to find essential parts inadmissible and then argue legal insufficiency — can be discerned in many pre-*Daubert* decisions as well.[70] Yet *Daubert*, together with its rationale of liberalizing the admissibility of scientific expert

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[66] *See* Dreyfuss, *supra* note 22, at 1797-1800 (maintaining that access to scientific knowledge limits need for restricting jury's role); Imwinkelried, *supra* note 44, at 566-71 (noting that lay jurors' lack of ability to understand scientific evidence is probable but that this is still in early stage of being empirically investigated). *But see* Sanders, *supra* note 5, at 77 (suggesting more comprehensible instructions to improve jury understanding).

[67] Gross, *supra* note 18, at 152.

[68] *Id.*

[69] *Id.*

[70] *See* Lunney, *supra* note 23, at 130-36 (describing pre-*Daubert* evidentiary approaches to admitting scientific evidence); *see, e.g.*, Lynch v. Merrell-Nat'l Labs., 830 F.2d 1190, 1194 (1st Cir. 1987) (holding that non-epidemiological studies were not of type reasonably relied upon by experts in particular field, as required by FRE 703); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 833 (D.C. Cir. 1988) (contending that determining whether scientific evidence is adequate is question of law). For a similar decision in the "Agent Orange" litigation, see *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp 1223, 1231 (E.D.N.Y. 1985), *aff'd* 818 F.2d 187 (2d Cir. 1987), in which Judge Weinstein argued that epidemiological studies "are the only useful studies having any bearing on causation." *See also* Sanders, *supra* note 20, at 1406-17 (discussing primacy of epidemiology in Benedectin cases). Sanders argues that to exclude "non-epidemiological evidence because better, epidemiological evidence exists is erroneous under a scientific validity standard." *Id.* at 1417.

evidence, its faith in the adversary system, and its admonition to focus upon methodology, apparently did not alter the trend. Courts still tend to rule evidence inadmissible and grant summary judgment on legal insufficiency.[71] By using this method, courts conceal that they are actually constructing their own view of what science holds true for the cases with which they deal.[72] The most problematic, and dangerous, consequence of these restrictive rulings is that they limit, if not preclude, "the availability of tort remedies for the injured toxic tort plaintiffs."[73]

III. A (VERY) SHORT OUTLINE OF DUTCH LEGAL LANDSCAPE (IN CIVIL CASES)

The Netherlands is a country within the Civil Law — or Continental — tradition. If nothing else, this means that the law is codified along divisional lines separating private and public law, as well as substantive law and procedural law. In contrast to the Federal Rules of Evidence in the United States, which govern both civil and criminal cases, evidentiary rules in the Netherlands do not apply equally to both types of cases. While civil cases are governed mainly by the statutory rules of evidence included in the Code of Civil Procedure (*Burgerlijke*

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[71] In the appendix to his article, Gross mentions six appellate toxic tort case that were decided after *Daubert*. In each of these cases, the trial court excluded scientific evidence and granted the defendant's motion for summary judgment. *See* Gross, *supra* note 18, at 171. All decisions were upheld on appeal. *See* Porter v. Whitehall Labs., 9 F.3d 607, 614-16 (7th Cir. 1993) (holding that expert testimony was not well-grounded in scientific method, and was properly excluded); O'Conner v. Commonwealth Edison Co., 13 F.3d 1090, 1106-07 (7th Cir. 1994) (holding that expert testimony not supported by scientific fact and methodology was properly excluded); Hayes v. Raytheon Co., No. 92-4004, 1994 U.S. App. LEXIS 8415, at *9 (7th Cir. Apr. 21, 1994) (finding that testimony of expert witness was insufficient to establish dispute of material fact); Sorensen v. Shaklee Corp., 31 F.3d 638, 648-49 (8th Cir. 1994) (holding that expert testimony on causation of mental retardation of children lacked sufficient scientific validity); Claer v. Burlington N. R.R. Co., 29 F.3d 499, 502-03 (9th Cir. 1994) (finding that reasoning and methodology underlying expert testimony failed to explain basis for conclusions and was not improperly excluded).

[72] *But see* Gross, *supra* note 18, at 164 (arguing that "if it is appropriate for the courts to make substantive scientific judgments on liability as a matter of law, they should not muddy the waters by pretending merely to apply procedural and evidentiary rules").

[73] *See* Lunney, *supra* note 23, at 109 (explaining that toxic tort plaintiffs' heightened burden of proof will curtail availability of tort remedies).

Rechtsvordering (*Rv*), completely revised in 1987), criminal cases are governed by the rules of evidence incorporated in the Code of Criminal Procedure.[74]

Civil proceedings in the Netherlands are characterized by six general principles. First, the proceedings are conducted in public,[75] and the court's decision needs to be motivated or argumentated. These requirements are meant to secure judicial impartiality.[76] Second, both parties are entitled to a proper hearing before the court: *audi et alteram partem*.[77] Third, in appearing before the court, the parties have a duty to retain counsel.[78] Fourth, the costs of litigation are to be borne by the litigants.[79] Fifth, judges supervise the proceedings; they do not

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[74] This division between evidentiary and procedural rules for civil and criminal matters presents at least one question the American legal system has faced as a consequence of the Supreme Court's analysis in *Daubert*. In light of the fact that FRE 702 — the rule the *Daubert* Court relied upon — applies to both civil and criminal cases, some federal courts have seriously debated whether some forensic sciences actually qualify as scientific evidence under the Supreme Court's interpretation of that rule. In *United States v. Starzecpyzel*, 880 F. Supp. 1027 (S.D.N.Y. 1995), the U.S. District Court for the Southern District of New York held that forensic document examination does not pass muster as scientific knowledge. *See id.* at 1030. Such expert evidence, the court stated, may be held admissible as "technical or other specialized knowledge" — the remaining part of FRE 702 — but courts may decide, in light of the fact that it is not a science and should thus not be so presented, to restrict this testimony with regard to the degree of certainty expressed. *See id.* at 1041-42. The decision in *Starzecpyzel* was subsequently followed by a decision of the U.S. Court of Appeals for the Armed Forces in *United States v. Ruth*, 42 M.J. 730, 732 (1995). Given the dividing lines between criminal and civil cases, *Daubert* in the Lowlands would not have that effect. On *Daubert*, *Starzecpyzel*, and issues of comparative law, see Petra van Kampen, Starzecpyzel *in Europe: Some Impressions from Holland*, paper presented at the 5th European Conference for Police and Government Handwriting Experts, The Hague, Nov. 15, 1996.

[75] *See* Article 18 sub 1 Rv (Code of Civil Procedure) (listing in subdivision 2 exceptions for procedures concerning divorce and separation, as well as procedures tied to painful conflicts regarding family matters, such as denial of paternity).

[76] Note that in the Dutch legal system the court, or more generally the trier of fact, ordinarily does not include lay-people. Trial by jury does not exist in criminal cases or in civil cases. Nevertheless, many civil disputes are currently decided by arbitration and other forms of alternative dispute resolution, which do involve some type of lay participation. The level of lay participation varies from decisions by one lay person to settlements by mixed panels, including lawyers and specialists in the area in which the dispute has arisen.

[77] *See* Article 45 sub 1 Rv.

[78] This principle rests on three grounds: (1) counsel is more knowledgeable than the parties themselves; (2) a duty to retain counsel furthers fairness of proceedings; and (3) the rule facilitates the actions of the court. The rule does not apply to proceedings before the courts of limited jurisdiction (*kantongerechten*). *See* P.A. Stein, COMPENDIUM VAN HET BURGERLIJK PROCESRECHT 20-21 (1990).

[79] Note, however, that legal aid is available to indigents. In addition, there is no

fully take part in them.[80] Last but not least, the plaintiff and the defendant are both entitled to a full hearing in two instances.[81]

When parties are preparing a lawsuit, provisional proof-taking can take place under the authority of the investigating judge; witnesses can be examined under oath, and the parties can request the investigating judge to appoint experts. In general, court-appointed experts appear more often than experts retained by the parties.[82]

Should the plaintiff decide to take his claim to court, that claim will usually be filed with the district court (*Rechtbank*). Once the district court decides that claim, both parties have a right to appeal to the Court of Appeals (*Gerechtshof*). The proceedings on appeal may include the introduction of fresh evidence on issues contested by the parties. The perspective of the appellate court is thus significantly different from that of an American Court of Appeals.[83] The highest level of the courts — the Court of Cassation (the *Hoge Raad der Nederlanden*) — can only decide matters of law, not fact.[84]

"American rule" in Dutch civil proceedings; the losing party is required to pay (part of) the costs of the winning party. *See* Article 56 sub 1 Rv. The court can decide to mitigate the harsh potential of this rule for reasons of fairness. *See* Article 57ab sub 1 Rv.

[80] In practical terms, this means that (1) the initiative to instigate civil proceedings cannot stem from the court, but only from one of the parties; (2) the court cannot decide matters not requested by the parties, nor can the court award more damages than parties asked for; (3) the parties are free to end their dispute at any time during the proceedings; (4) facts not contested by the parties are assumed to be true; the court can only direct proof-taking on contested matters, *see* Article 176 sub. 1 Rv; and (5) when one of the parties offers to prove a contested matter through the testimony of witnesses, the court must allow this party to proceed. Note that courts are completely free to render a decision on legal grounds different from those asserted by the parties. In addition, courts may, *ex officio*, (a) require parties to provide information regarding the matters at stake; (b) require the parties to provide evidence; and (c) direct the hearing of witnesses. *See* Stein, *supra* note 78, at 26-30.

[81] This means that both parties generally have a right to file an appeal against the decision of the original trial court, and to have the case decided anew by the higher court to which they appeal.

[82] This is true not just for the pretrial stage, but for the procedure as a whole. In this respect, the Dutch system can be considered to be a typical Continental system. *See generally* F. Terré et al., L'EXPERTISE DANS LES PRINCIPAUX SYSTÈMES JURIDIQUES D'EUROPE (1969).

[83] Contrary to criminal cases, the parties can agree to address the appellate court as a court of first instance (*prorogatie van rechtspraak*).

[84] Criminal cases are processed in a similar fashion, albeit in criminal matters, a hierarchically structured national prosecution service takes care of all criminal prosecutions.

In principle, the burden of proof is allocated to the party claiming the legal consequences of a rule of substantive civil law. In other words, the plaintiff has to present sufficient facts from which the legally relevant consequences can be inferred.[85] When contested by the adverse party, the plaintiff will have to prove these facts.[86] This principle governs all civil proceedings, unless a specific rule or the principle of fairness requires otherwise. In this respect, it is important to note that many provisions of the Civil Code as well as case law of the Court of Cassation constitute exceptions to the rule, and shift at least part of the burden of proof to the other party. The burden is shifted either by establishing legal presumptions,[87] or by requiring certain actions to take place according to preset rules.[88] Particularly in the area of labor and tort law, shifting the burden of proof from the plaintiff to the defendant has been the Court of Cassation's primary remedy for the inability of plaintiffs to prove all legally relevant facts in toxic tort cases.

The standard of proof is "preponderance of evidence" (more likely than not). This implies that the party bearing the burden of proof must meet this standard in order to succeed. Although the Code of Civil Procedure lists some types of acceptable evi-

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Petty offenses, like petty torts, are dealt with by the courts of limited jurisdiction, while serious crimes are brought before the district court. Both parties can appeal the decision, which will be considered by the court of appeals, trying cases de novo. Should questions of law arise in relation to the final decision of the appellate court, parties can appeal to the *Hoge Raad der Nederlanden*. Different from civil matters, however, the courts play a very active role in criminal matters.

[85] For a recent decision of the Dutch Court of Cassation to that effect, see Winterthur/Schutte, HR 23 september 1993, NJ 1994, 226.

[86] *See* Article 177 Rv; *see generally* INTRODUCTION TO DUTCH LAW FOR FOREIGN LAWYERS 205 (Jeroen M.J. Chorus et al. eds., 2d ed. 1993) [hereinafter DUTCH LAW]. In practice, this finds expression in the "brocard," "he who puts forward a claim, has to prove it" (*hij die stelt, bewijst*).

[87] Dutch civil law does not include irrefutable presumptions, so proof to the contrary may refute any legal presumption.

[88] In transferring property, for example, the Civil Code requires a special juristic act of conveyancing called *traditio* ("levering"). In real estate transactions, this act requires the execution of a legal instrument (document; "*notariële akte*") and registration in a special public register. *See* DUTCH LAW, *supra* note 86, at 207. The existence of the instrument and registration establishes a legal presumption that property has indeed been transferred. Proof to the contrary is possible, yet the burden rests upon the party denying that the property was transferred. Labor law and the law of succession, in particular, are areas in which one traditionally will find substantive obligatory rules that affect the allocation of the burden of proof.

dence, such as documentary evidence, witness testimony, and expert opinions, the list is not exhaustive. The party can meet its burden of proof by introducing *all* relevant evidence (including statistical evidence),[89] unless the Code requires that particular acts be proven by only certain documentary material.[90] Nevertheless, even in the latter case, the judge is free to weigh the evidence as she sees fit.[91] There is one rule limiting that freedom; the judge is obliged to follow the contents of authentic acts.[92]

IV. TOXIC TORT: THE DUTCH EXPERIENCE IN ASBESTOS

Toxic tort litigation is a relatively recent vintage in the Netherlands. The first asbestos case reached the Court of Cassation in 1980. In the years that have followed, the Dutch courts have decided about a dozen asbestos cases, almost all in favor of the plaintiffs, while a few are still awaiting judgment.[93] As Vinke

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[89] The Court of Cassation explicitly acknowledged the use of statistical evidence in Binderen/Kaya, HR 10 december 1982, NJ 1983, 687. In that case, the Court found statistical evidence sufficient to reverse the burden of proof. *See* Niels Frenk, *Toerekening naar kansbepaling*, NEDERLANDS JURISTENBLAD 482 (1995) (discussing statistics and proof more elaborately); A.W. Jongbloed & M.L. Simon, *Waarheden, halve waarheden en onwaarheden: statistiek en bewijsrecht*, NEDERLANDS JURISTENBLAD 891 (1995) (same).

[90] *See* Article 179 Rv.

[91] *See* Article 179 sub. 2 Rv.

[92] Article 183 sub. 2 Rv defines an authentic act as an act made out in the required format by a competent authority. According to Article 184 sub. 2 Rv, authentic acts (and other signed acts meant to serve as evidence) are conclusive proof of the truth of the statements contained therein, unless this would result in consequences upon which parties cannot freely decide.

[93] For an overview, see Paul Swuste et al., *Van individuele 'asbestprocessen' naar een asbestfonds?* ARBEIDSOMSTANDIGHEDEN 119, 121 (1996) (listing 13 personal injury cases related to asbestos, including two appellate cases). A recent analysis of 211 asbestos-related dossiers shows that since 1992, about 20 cases have been filed with the court. By 1997, seven of those cases had been decided, while the rest still await final judgment. *See* J. de Ruiter, *Asbestslachtoffers*, ADVIES IN OPDRACHT VAN DE STAATSSECRETARIS VAN SOCIALE ZAKEN EN WERKGELEGENHEID § 3.6 (Mar. 1997).

In virtually all cases mentioned by Swuste, the court granted the plaintiffs' request for compensatory damages. The exceptions are *Werner/Wilton Feijenoord*, Pres. Rb. Rotterdam, 22 januari 1992, KG 1992, 70, in which the defendant successfully claimed that the state of the art did not require safety measures at the time the employee was exposed to asbestos (1959-72), and *Van Os/Wilton Feijenoord/RDM*, Pres. Rb. Rotterdam, 4 januari 1996, TMA 1996-2, in which the court held that the plaintiff could no longer file suit in light of the statute of limitations. The statute of limitations in these cases is 30 years (article 3:310 Civil Code). *But see* J.M. van Dunné, *Verjaring van aansprakelijkheid van werkgevers voor de*

and Wilthagen have argued, the "near-zero" situation that existed in Holland until 1993 could easily be explained if the country used little or no asbestos, and few people were actually in contact with this hazardous substance.[94] That, however, does not correspond with the actual facts. Between 1945 and 1977, Dutch companies processed tons of asbestos. In 1984, it was estimated that about 40,000 employees were in daily contact with the substance.[95] Moreover, the incidence of mesothelioma is apparantly higher in the Netherlands than in other countries.[96] In the next twenty-some years, an estimated 20,000 people will die of mesothelioma as a result of their occupation-related exposure to asbestos; another 20,000 will die of asbestos-related lung cancer.[97]

Although international consensus on asbestosis was reached as "early" as 1929,[98] the Dutch followed only in 1942.[99] Additionally, while Great Britain recognized asbestosis as an occupational disease in 1931, the Dutch did not do so until almost 15 years later, in 1946.[100] In 1968, mesothelioma was first mentioned by

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asbestziekten van werknemers, De betekenis van de begrippen 'gebeurtenis' en 'bekendheid met de schade als grondslag van de vordering' voor de verjaring TMA 17, 29 (1996-2) (stating that strong reasons exist to argue that statute of limitations should start running after disease has manifested). Most of these suits were filed in summary proceedings — an abbreviated version of normal civil proceedings in light of the urgency of the claim — and aimed at receiving advance payment. The advanced payments range from 100.000 to 150.000 guilders ($50,000 to $75,000). *See id.* at 18.

[94] *See* Harriet Vinke & Ton Wilthagen, *Asbest arrest Hoge Raad: het hek van de dam?* RECHTSHULP 8-9 (1993).

[95] *See id.* at 9.

[96] *See id.*

[97] *See* de Ruiter, *supra* note 93, at 6-7. These figures do not include non-occupational exposure and indirect exposure to asbestos. Such exposure was likely to result from many companies' long-standing practice of having employees wash their own clothes.

[98] Referring to 1929 as "early" is, however, quite dubious in light of the recurring articles noting that medical researchers knew about the adverse health effects of asbestos well before 1929, but did not disclose this information for want of industrial support for their research. *See* David E. Lilienfeld, *The Silence: The Asbestos Industry and Early Occupational Cancer Research — A Case Study*, 81 AM. J. PUB. HEALTH 791, 791-93 (1991) (suggesting that insurance industry and medical community participated in suppression of asbestos data during early 1900s).

[99] *See* Lex Burdorf et al., *A History of Awareness of Asbestos Disease and the Control of Occupational Asbestos Exposures in the Netherlands*, 20 AM. J. INDUS. MED. 547, 548 (1991) (presenting table comparing first suggestion and first case description of relationship between asbestos exposure and disease in scientific literature).

[100] *See* P.H.J.J. SWUSTE ET AL., ASBEST: HET INZICHT IN DE SCHADELIJKE GEVOLGEN IN DE

the Labor Inspection as an occupational disease.[101] Asbestos legislation followed first in 1977 (prohibiting asbestos spraying and the use of crocidolite).[102] Three other Asbestos Regulations followed in 1983, 1988, and 1993, the latter prohibiting all vocational use of asbestos.[103]

Meanwhile, employees who developed asbestos-related diseases as a result of their exposure to the substance could not file suit against their employers. Until 1967, the so-called "pacification" article in the Accidents Act severely restricted the ability to file for damages under article (7A:)1638x *Burgerlijk Wetboek* (BW) of the Civil Code[104] for violation of a duty of care on the part of an employer. Disabled employees received their compensatory damages from social security laws, not from the courts.[105]

Ten years later, in 1980, the first asbestos case to reach the Court of Cassation was filed under article 1638x BW, an article requiring the employer to do anything reasonably necessary in order to protect the safety of his employees.[106] The plaintiff argued that he had developed asbestosis as a result of his exposure to asbestos in 1961 and 1962 while working for the defendant. In awarding compensatory damages, the court of limited

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PERIODE 1930-1965 14 (1988). However, it is worth noting that in 1935 the Amsterdam court of limited jurisdiction decided that asbestosis is an occupational disease that can be avoided by safety measures. *See* J.M. van Dunné & E.E.I. Snijder, *Asbest en aansprakelijkheid, in* ASBEST EN AANSPRAKELIJKHEID 132-33(J.M. van Dunné ed., 1994) (citing Ktg. Amsterdam, Mar. 29, 1935, NJ 1935, at 1293).

[101] *See* Swuste et al., *supra* note 93, at 39.

[102] In 1971, prompted by a publication on mesothelioma among workers in a shipyard, the Dutch Labor Inspectorate issued guideline P-116, stating that a level of more than 12 fibers per milliliter was unacceptable. *See* Burdorf et al., *supra* note 99, at 553; de Ruiter, *supra* note 93, at 9. However, these guidelines were not legally enforced. *Id.*

[103] *See* P.H.J.J. Swuste, *Asbest, feiten en maatregelen, in* ASBEST EN AANSPRAKELIJKHEID 12 (J.M. van Dunné ed., 1994); de Ruiter, *supra* note 93, § 2.3. For an English overview of the same, see Burdorf et al., *supra* note 99, at 548.

[104] Since 1 April 1997, article 7A:1638x BW no longer exists. The case law based upon the article has resulted in the formation of a new article, article 7:658 BW. This new provision states that the employer is liable for damage incurred by the employee in his services for the employer, unless the latter shows (a) that he discharged his duties, or (b) that the damage resulted from intent or recklessness of the employee. *See generally* A.T. Bolt, *De uitdijende reikwijdte van het aansprakelijkheidsrecht? in* A.T. Bolt & J. Spier, *De uitdijende reikwijdte van de aansprakelijkheid uit onrechtmatige daad,* PREADVIES NEDERLANDSE JURISTEN-VERENIGING 87-112 (1996) (discussing art. 1638x BW and its progeny).

[105] *See* de Ruiter, *supra* note 93, at 40; Dunné & Snijder, *supra* note 100, at 133; Vinke & Wilthagen, *supra* note 94, at 9.

[106] *See* HR 7 maart 1980, NJ 1980, 365.

jurisdiction noted that the employer had not contested the plaintiff's claim that he had not been exposed to asbestos in any other occupation preceding or following the one at issue. In light of the fact that asbestosis can only be caused by exposure to asbestos, the court felt it was sufficiently proven that the defendant was liable for damages. On appeal, the district court more specifically argued that the plaintiff's disability could be presumed to be caused by his activities in service of the defendant, unless the defendant-employer could present proof to the contrary. The Court of Cassation agreed with this factual presumption of liability and upheld the district court's decision.

In 1984, a suit was filed against Nefabas, an asbestos producing and processing company, claiming that the company was responsible for the plaintiff contracting asbestosis. The plaintiff alleged that Nefabas did not take reasonable safety precautions, although the company was, or should have been, aware of the dangers of asbestos.[107] The court of limited jurisdiction thereupon ordered the plaintiff-employee to prove that Nefabas had failed to take such reasonable precautions. Having failed that burden in the eyes of the court, the plaintiff's claim was subsequently denied; a decision affirmed by the District Court. The Court of Cassation, however, reversed. It argued that when specific safety regulations do not exist, the defendant-employer has the obligation to investigate which dangers are tied to the work it requires. This also means that when the health of its employees is affected, and suit is filed against it, the defendant must show how and when it was informed about the dangers, what it did to counter these dangers, as well as the reasons why it decided that certain safety measures could not reasonably be expected from it.[108] In other words, while the employee "only" needs to show that there is a connection between his previous occupation and the disease he contracted, the employer has to show why it cannot be held liable for the plaintiff's injuries.[109]

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[107] *See* HR 6 apr. 1990, NJ 1990, 573 (Janssen-Nefabas).

[108] Note that although the defendant-employer may need to show the "state of the industry" — both in and outside the country at the time — the Court of Cassation explicitly stated that this standard does not free an employer who knew or should have known about the dangers of liability. *See* van Dunné, *supra* note 93, at 20.

[109] Many writers have argued that the decision in *Janssen-Nefabas* fits within a series of cases decided prior to that case. *See, e.g.*, van Dunné & Snijder, *supra* note 100, at 132-39.

Notwithstanding this fortuitous decision for the victims, relatively few actions took place on the claimant front; a development no doubt influenced by the high level of social security in the Netherlands. As Vinke and Wilthagen have argued, a high level of social security is usually an indication of a strongly collectivized society, in which the consequences of calamities are carried by the collective.[110] Such a society, they proceed, seldom has an antagonistic character.[111] However, while the system of social security became the subject of much political debate in the early nineties, and politics started nibbling its edges,[112] the Court of Cassation gave a final blow to the legal position of the defendant-employer in the third asbestos case to reach that Court. After reiterating that the employer is liable for the adverse health effects of a dangerous substance if he does not take adequate precautions, the Court in *Erven Cijsouw v. De Schelde,*[113] stated that the mere fact that a particular hazardous effect was unknown at the time the incident occurred does not disculpate the defendant, unless the *defendant* shows that the safety measures required at the time — which the employer did not take — could not have avoided the incident. Eight years after the plaintiff's death, the Court of Appeals on remand recently held that De Schelde did violate its duty of care, and granted compensatory damages to the plaintiff's heirs.[114]

Many writers have argued that the decision of the Court of Cassation in *Erven Cijsouw* comes dangerously close to establishing strict liability for employers, and have predicted an increase of asbestos-related cases in the coming years.[115] Indeed, since

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[110] *See* Vinke & Wilthagen, *supra* note 94, at 12.

[111] *See id.*

[112] *See id.*

[113] *See* HR 25 june 1993, NJ 1993, 686; *see also* HR 1 oct. 1993, *RvdW* 1993, 189 (*Lekkende kruik* II).

[114] The plaintiff was diagnosed with mesothelioma in June 1988. He filed suit against the shipyard Koninklijke Maatschappij De Schelde in December 1988. Three months later, he died. For more elaboration on this case and the technical aspects of it, see J.M. van Dunné, *Het De Schelde-arrest en aansprakelijkheid voor asbestziekten, in* ASBEST EN AANSPRAKELIJKHEID 19 (J.M. van Dunné ed., 1994). *See also* J. Spier, *Asbest en aansprakelijkheid, in* ASBEST EN AANSPRAKELIJKHEID 35 (J.M. van Dunné ed., 1994). Note that the Dutch legal system does not allow for punitive damages to be awarded to plaintiffs. *See, e.g.*, van Dunné, *supra*, at 32.

[115] *See* M.G. Faure & T. Hartlief, *Een Asbestfonds als alternatief voor de aansprakelijkheid van de werkgever?*, SOCIAAL RECHT 37 (1996-2); Swuste et al., *supra* note 93, at 119; van Dunné,

1993, at least one hundred — but probably more — claims for compensatory damages were filed with the relevant agencies.[116] In light of the recent decision of the appellate court in *Erven Cijsouw*, finding the defendant-employer liable for compensatory damages, more claims are to be expected. Yet, notwithstanding the arguments put forth by the Court of Cassation, many claimants seem to find themselves either empty-handed or dead at the end of the settlement process that usually precedes filing suit with the courts.[117] Other than running out of time, among the problems they experience are the applicable statute of limitations,[118] the inability to file a claim with the relevant employer, and the inability to establish causation. Although the burden of proof has been lifted from the plaintiff's shoulders, he still needs to identify the liable defendant-employer. For an employee having changed jobs frequently in the relevant period of time, identifying the employer may be nearly impossible.[119] Meanwhile, it is no less difficult to file suit against an employer who has since disappeared or gone bankrupt.[120] For people

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supra note 93, at 17; Vinke & Wilthagen, *supra* note 94, at 9.

[116] de Ruiter reports that between 1992 and 1997, 211 suits for compensatory damages were filed; half of them date from 1993. The author estimates that these 211 dossiers represent about 40% of all claims currently filed in the Netherlands. *See* de Ruiter, *supra* note 93, at 15. Most of these claims invoke article 7A:1638x BW as the cause for action. *See id.* at 16.

[117] Of the 211 cases analyzed by de Ruiter, about 70 had been closed by December 1996. In about 60% of these cases, the claimants had run into problems related to establishing causation, finding the employer liable, and the statute of limitations. *See* de Ruiter, *supra* note 93, at 17. Thirty-one percent of the claimants died before the process for compensatory damages came to an end. *See id.* It takes the defendant party about nine months to express a willingness to settle the claim. It takes another four to five months before a settlement can be negotiated. *See id.* at 21.

[118] *See* de Ruiter, *supra* note 93, at 15. The author estimates that the statute of limitations is the main problem in about 15% of all cases. *See id.* at 22.

[119] *But see infra* note 137 (citing *DES-daughters* case). The rule of alternative causation that was adopted in that case may alleviate plaintiff's problems should it be adopted in asbestos cases. The victim can simply file suit against one of his former employers. The employer then will need to show that the disease contracted by the plaintiff could not have been caused during the time frame the plaintiffs worked for him. *See* Spier, *supra* note 114, at 44; van Dunné, *supra* note 93, at 27. According to Bierbooms and Brans, there is one case, decided by a court of limited jurisdiction in Rotterdam, in which the rule of alternative causation was indeed invoked in an asbestos case. *See* P.F.A. Bierbooms & E.H.P. Brans, *Aansprakelijkheid voor asbestschade in Nederland en de Verenigde Staten. Enige problemen bij de civielrechtelijke benadering van massa-schade, in* ASBEST EN AANSPRAKELIJKHEID 91-92 (J.M. van Dunné ed., 1994).

[120] Overall, it is estimated that bankruptcy of the employer in 5% to 10% of all cases

suffering from lung cancer, it is moreover still very cumbersome to establish a causal link between asbestos exposure and the disease, in light of other possible causes, such as smoking.[121]

Even assuming that the employer can be found and that a causal link can be established, more problems may arise. For example, what did the state of the art require at the time? The court in *Werner v. Wilton Feijenoord*[122] held that in light of the state of the art, the defendant did not need to take certain protective measures against asbestos exposure in 1971. However, the court in *Wijkhuizen v. De Schelde*[123] argued that the employer should have taken identical protective measures in 1953.[124]

The inability of asbestos victims to obtain compensation and an acknowledgment of guilt for the actual damage they suffered within a reasonable amount of time — or at all in light of the problems in finding the employer — has attracted much debate in the Netherlands. For two years, the focal point of attention has been the creation of some sort of compensation scheme.[125] Although the government has always welcomed such a plan, it has, as of yet, refused to take financial responsibility for it. Instead, the government argues that it is first and foremost a problem of employers.[126] The employers, however, refuse to

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amounts to the claimant not being compensated for the damage suffered. *See* de Ruiter, *supra* note 93, at 22.

[121] *See* A.J. Van & H.G.T. Nijs, *Asbest, tabaksrook en longkanker. Aansprakelijkheidsverdeling bij verschillende samenwerkende causale factoren*, TMA 45 (1996-3) (arguing for epidemiological criterium to establish interaction between different factors, and opting for distribution of liability based on risk contribution). de Ruiter estimates that in about 25% of all cases, the claimant is unable to establish causation for a variety of reasons. *See* de Ruiter, *supra* note 93, at 22.

[122] Pres. Rb. Rotterdam 22 january 1992, KG 1992, 70.

[123] Pres. Rb. Middelburg 1 june 1995, TMA 1995-6.

[124] *See also* Rouwhof/Eternit Pres. Rb Almelo 7 july 1994, TMA (1994-96) (arguing that protective measures against mesothelioma were required from mid-1970s on); Bierbooms & Brans, *supra* note 119, at 89; Swuste, et al. *supra* note 93, at 121-22. In cases concerning who should bear the costs of cleaning the soil from pollution, the Court of Cassation solved a similar problem by deciding upon a particular date — 1 January 1975 — on which the polluters should have been aware of the fact that their activities would cause the government material damage. *See* Van Wijngaarden/Staat and Staat/Akzo Resins, HR 24 apr. 1992, NJ 1993, 643-44.

[125] *See, e.g.*, L. Dommering-van Rongen, SCHADEVERGOEDING DOOR FONDSVORMING (1996); de Ruiter, *supra* note 93, chapter 4; Faure & Hartlief, *supra* note 115.

[126] *See* van Dunné, *supra* note 93, at 26-27. As van Dunné contends, however, the argument that the government should contribute to the fund seems justified in light of its very slow reaction to the dangers of asbestos. *See id.*

pay for anything other than the damage for which they are legally liable.[127] At the same time, the insurers hold that they cannot be required to pay the costs of something for which they have never collected premium and reserve money. Still, and notwithstanding the problems that may arise in this context, some believe a compensation fund is the best available means to solve the asbestos problem. In light of the move towards strict liability, the rise in the amount of immaterial damages the courts have awarded in general,[128] the fear of more profound changes in the Dutch system of social security,[129] and the ever growing number of people falling victim to lung cancer and mesothelioma as a result of asbestos exposure, those supporting a compensation fund fear that the failure to establish a fund may endanger the corporate lives of many, as well as future compensation for asbestos victims.[130]

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[127] *See* de Ruiter, *supra* note 93, at 26; Rene Didde, *Waarborgfonds voor slachtoffers asbeststof*, DE VOLKSKRANT (8 Apr. 1995); van Dunne, *supra* note 93, at 26-27.

[128] For a recent analysis, see Bolt, *supra* note 104, at 344-51; M.G. Faure et al., *Juridische aspecten van het beroepsziektenonderzoek: Mogelijke toename van claims op de werkgever? in* M.G. FAURE & T. HARTLIEF, VERZEKERING EN DE GROEIENDE AANSPRAKELIJKHEIDSLAST 37 (1995).

[129] From their analysis of the changes in the labor-related system of social security, Faure et al., *supra* note 128, § 3, conclude that the government's plans to dismantle the social security system may indeed increase the number of claims filed against employers. *Id.* at 85.

[130] *See* Spier, *supra* note 114, at 48; van Dunné, *supra* note 93, at 27. Around the same time this article was submitted for publication, in April of 1997, newspaper reports broke about the the Ministry of Defense's flagrant disregard for asbestos dangers in the NATO command center (the Cannerberg) in the Southern Netherlands. Although the Ministry of Defense had been warned about the presence of asbestos in the Cannerberg throughout the 1970s and '80s, it took no protective measures. In September of 1992, the bunker closed and the command center moved elsewhere. It is estimated that more than 8000 military personnel and civilians were exposed to asbestos in the bunker and other military centers in the Netherlands in all those years. The Ministry of Defense has since aknowledged liability for asbestos-related diseases of its employees.

In June 1997 the Dutch government more fully aknowledged its responsibility in asbestos litigation. Following the report of Professor de Ruiter, *supra* note 93, the Dutch government, on June 6, 1997, stated that a special fund should be established for those victims who are unable to file suit against their former employers. The fund is meant to provide the victims with partial compensation; the government does not seek to fully compensate the victims. Additionally, the government will establish a special institute to legally assist victims of asbestos in the Netherlands. Finally, the government announced that it would prolong the statute of limitations for asbestos cases, currently 30 years, in order to allow asbestos victims to receive compensation when asbestos-related diseases manifest themselves after 30 years. The extention of the statute of limitations applies only to those who have worked for the Ministry of Defense, however. The statute of limitations will re-

V. HALCION AND DES: TORT LAW IN HOLLAND

Between the asbestos cases of *Janssen v. Nefabas* and *Erven Cijsouw v. De Schelde,* Dutch courts were presented with two other toxic tort cases. One case revolved around Halcion, a sedative produced by the Upjohn company. The other involved Diethystilbestrol (DES), taken by more than 200,000 pregnant women between the 1950s and 1970s.[131]

Halcion was registered for the Dutch market in 1977. Barely two years later, the registration was suspended and later withdrawn by the Commission in charge.[132] The adverse health effects claimed to arise from the drug included suicide attempts, severe anxiety, headaches, and loss of memory.

After Halcion was withdrawn from the market, twenty-six plaintiffs filed suit against Upjohn, for both registering Halcion and failing to warn against the adverse and dangerous health effects of the drug.[133] The district court denied the claim. Among other things, the court held that Upjohn could reasonably rely upon the restraint of medical practitioners, who could hardly have failed to notice that Halcion was a powerful drug compared to other sedatives.

On appeal, the Court of Appeals stated that a drug is defective when it does not possess the safety that one expects in the given circumstances. In principle, the consumer need not expect health effects she has not been warned against by the manufacturer.[134] The court subsequently concluded that Upjohn could be found liable for failure to warn, should it be established that the plaintiffs indeed suffered the adverse health effects they claimed. Further, the court held, Upjohn could not rely upon

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main unchanged for all other asbestos-related cases, though the government has asked employers to voluntarily withdraw their arguments regarding the statute of limitations when faced with suits by their former employees. Algemeen Nederlands Persbureau (6 June 1997).

[131] It is estimated that in a 25-year time frame (1950-1975), between 189,000 and 378,000 women in the Netherlands were treated with DES. *See* T.H.J.M. Helmerhorst et al., *Nieuwe Richtlijnen voor gynaecologisch onderzoek bij DES-dochters,* NEDERLANDS TIJDSCHRIFT VOOR GENEESKUNDE 2065 (1992).

[132] HR 30 june 1989, NJ 1990, 652.

[133] *Id.*

[134] *Id.* The appellate court relied upon the definition of article 6: 186 BW (product liability), itself the result of an European Union guideline on product liability, which came into effect in 1992.

the restraint of doctors in prescribing the drug, nor the registration of the drug by the relevant Commission.

In order to establish whether the plaintiffs suffered adverse health effects, and what those adverse health effects were, the court appointed three medical experts: a pharmacologist, a psychiatrist, and a practitioner/specialist.[135] After selecting the experts and receiving their joint report, the Court of Appeals upheld the district court's denial of eleven plaintiffs' claims, while it reversed that decision for the fifteen remaining plaintiffs. With regard to the latter, the court declared that Upjohn had indeed acted unlawfully towards them by registering the drug and by failing to warn against the harmful consequences of its use. In addition, the court awarded damages to these plaintiffs.[136]

Meanwhile, the Court of Cassation struggled its way through another toxic substance: Diethystilbestrol (DES).[137] Between the early 1950s and mid-1970s, medical practitioners in the Netherlands frequently prescribed DES — a non-licensed drug, produced and distributed by more than two hundred different manufacturers — to pregnant women in order to prevent miscarriages or early birth.[138] In the early 1980s, it appeared that a significant number of the females born of mothers who used DES suffered from a particular type of cancer (carcinomen in the uro-genital system). Six of these women then filed suit against ten pharmaceutical companies that had sold the drug between 1953 and 1967. These women claimed that the pharmaceutical industry in general, and the pharmaceutical companies in the Netherlands in particular, acted unlawfully by consciously or

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[135] Before the court selected the experts, Upjohn filed an appeal on point of law with the Court of Cassation. The Court of Cassation decided that the definition of "defective product" used by the Court of Appeals was justified.

[136] *See* HR 20 sept. 1996, NJB 1996, nr. 178C. Four appellants received compensatory damages of 90.000 guilders; five received 56.250 guilders; and six received 22.500 guilders. *See* Dommering-van Rongen, *supra* note 125, at 19. Upjohn again filed for an appeal on points of law. Again, however, the Court of Cassation denied the appeal. HR 20 september 1996, NJB 1996, nr. 178C.

[137] HR 9 oct. 1992, NJ 1994, 535. The lawsuit was initiated by six plaintiffs, generally called "DES-dochters" (DES-daughters), against ten chemical companies: Bayer Nederland BV; Brocacef BV; Centrafarm BV; Dagra BV; Duphar Nederland BV; Medicopharma BV; Nogepha BV; Pharbita BV; Pharmachemie BV; UCB Pharma Nederland BV.

[138] *See* A.J. VAN, ONZEKERHEID OVER DADERSCHAP EN CAUSALITEIT (1995).

negligently accepting the risk that DES caused severe adverse health effects to the plaintiffs and their descendants. In response to the claim, the defendants argued that there was no established causal relationship between the use of DES and the plaintiffs' health problems. Even assuming that such a relation could be established, the defendants argued, no such producer could be identified as the producer of the particular drug each of the mothers claimed to have taken during pregnancy. The District Court of Amsterdam agreed with the latter argument, and in 1988 denied the claim.[139]

In denying the claim, the district court referred to article 6:99 BW of the "new" Civil Code, which was to become effective on January 1, 1992. That provision regulates liability based upon "alternative causation"; a rule not incorporated in the "old" Civil Code. It states that:

> When the damage may have resulted from two or more events for each of which a different person is liable, and where it has been determined that the damage has arisen from at least one of these events, the obligation to repair the damage rests upon each of these persons, unless he proves that the damage is not the result of the event for which he himself is liable.

The district court stated that the rule was not applicable to the facts at issue, as it requires that the responsible party to be at least among those named as the defendants in the suit filed. Because the plaintiffs' injuries may have resulted from the actions of a party not named in the suit, it was impossible to conclude that the culprit was indeed among the ten defendants named by the daughters.[140]

Plaintiffs appealed, but were, initially, not very successful. In 1990, the Amsterdam Court of Appeals upheld the decision in first instance.[141] Although article 6:99 BW was not yet in force as a *statutory* rule, the Court of Appeals held that it already existed at the time the alleged acts had taken place (1953-1967). However, the court held that article 6:99 BW was not applicable to the facts at issue. The court stated that although making the

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[139] *See* Rb. Amsterdam, 25 may 1988, TvC 1988, at 274.

[140] *See id.*; *see also* HR 9 oct. 1992, NJ 1994, 535, at 2486.

[141] *See* Hof Amsterdam, 22 nov. 1990, TvC 1991, at 123; *see also* HR 9 oct. 1992, NJ 1994, 535, at 2475-77.

drug available to the general public might be considered an illicit act on the part of the producer, it could not be regarded as a tort towards each of the daughters, as it is unlikely that each producer is responsible for the damage done to all victims. In order for it to be a tort, the plaintiffs needed to prove a connection between themselves and the individual defendants, such as particular sales of the drug by one or more of the companies to the individual mothers.[142] Such particular acts, however, were not alleged by the daughters.

The court further argued that even if it could be established that one or more of the defendants had committed a tort, the rule of alternative causation required that the plaintiffs assert, and establish, who exactly were among the liable entities. Here too, the Court of Appeals argued, the daughters did not — and could not — meet their burden of bringing forward facts and circumstances to prove the circle of producers liable for their damage.[143] In other words, the daughters did not — and could not — show sufficient cause for action.

The Dutch Court of Cassation strongly disagreed.[144] In its decision, the Court of Cassation argued that *assuming* that the plaintiffs could establish a causal relationship between the consumption of DES by the mothers and the adverse health effects experienced by the daughters, the rule of alternative causation was applicable, and was so in 1953.[145] The wording of article 6:99 BW, the Court held, does not require a demonstration of specific conduct on the part of the defendants, as the appellate court held.[146] Indeed, the Court of Cassation argued, applying the rule to the situation at issue conformed to the meaning of the article, which is to avoid the injustice that arises when vic-

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[142] *See* HR 9 oct. 1992, NJ 1994, 535, at 2476, §§ 7-8.

[143] *See id.* §§ 10-12.

[144] *See id.* An English summary of the case can be found in TMA 19 (1993-1).

[145] Note that the rule of alternative causation only came into force in January 1992; a forerunner of the article was proposed by Meijers in 1961. The Court of Cassation, however, argues that "it should be assumed that the rule of article 99 applies to both the period of 1953 to 1967 — when the mothers of the DES-daughters took the drug — and later onwards, when the consequences manifested itself in the daughters." After all, the Court stated, when it was proposed in 1961, it represented the then governing opinions on law and liability. For more elaboration on this subject, see P. Ingelse, *Hoge Raad in DES-arrest: ruim baan voor artikel*, 6:99 BW, 42 NEDERLANDS JURISTENBLAD 1403 (1992).

[146] *See* HR 9 oct. 1992, NJ 1994, 535, § 3.7.1.

tims are left empty-handed because they are not able to identify the particular behavior that caused the damage done.

Thus, the onus was not upon the plaintiffs (the individual daughters) to establish that the drug caused their particular injuries. Rather, once the plaintiffs have proved that (a) the company did bring the drug onto the market and is liable for that action; (b) that there are other companies manufacturing the drug and liable for a defect;[147] *and* (c) the plaintiffs suffered damage as a result of the use of the drug, but cannot establish from which producer the drug originates, the onus is on each of the companies to prove that the drugs *they* produced did not cause the adverse health effects in each individual case.[148] In other words, if the company cannot prove the absence of a causal relationship between its sales of the drug and the claimed effects, then the company is liable for the plaintiffs' damages. To this end, it is irrelevant whether the plaintiffs establish who exactly belonged to the group of liable entities, or whether each of these entities can still be sued for their conduct. Because identification of all producers is virtually impossible, such would be an unreasonable requirement to place upon the plaintiffs.[149] The Court argued that in light of the potential of insolvent producers and the claimants' need to file multiple suits in order to receive full damages, liability should not be limited to market share. Instead, the producers are joint and severally liable.[150]

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[147] It may be subsequently established that a producer who brought the damage-causing drug onto the market is not liable because it has not done anything wrong in that process. The Court of Cassation argues that such does not relieve the remaining producers from their liability for the whole, unless such liability would be unreasonable in light of the circumstances, such as the likelihood that the damage was caused by a non-liable producer. *See id.* § 3.7.6.

[148] *See id.* § 3.7.5.

[149] *See id.* § 3.7.3.

[150] The Court of Cassation's refusal to limit liability to market share, advocated by the Advocate General Hartkamp, attracted much criticism in light of the fact that individual producers are now liable for more damage than they actually caused. Many legal commentators have argued that the Court should have followed the market share liability, like the New York Court of Appeals did in *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1078 (N.Y. 1989) (explaining practical reasons for adopting market share theory). *See, e.g.*, J. Akkermans, *Oorzakelijk verband, in* ONRECHTMATIGE DAAD. BW-KRANT JAARBOEK 1996, at 55-59 (M.E. Franke et al., eds., 1996); L. Dommering-van Rongen, *Het DES-arrest: geen marktaandeelaansprakelijkheid maar aansprakelijkheid voor de gehele markt*, WPNR 6089, 280

The rationale behind the argument is quite clear: individual plaintiffs in toxic tort cases are not to be burdened with the problems tied to the existence of multiple manufacturers. "All" they need to do is identify one manufacturer or distributor of the toxic agent and establish its liability. How and to what extent the damages paid to the consumers will be allocated amongst all manufacturers and distributors is a matter that should not concern the individual consumers.[151]

Less clear, but potentially far-reaching are the consequences of DES for producers and insurers. Should article 6:99 BW develop into a more common doctrine in these and similar cases, legal commentators have argued, a host of severe financial problems are likely to arise in its wake. Such results would lead, in turn, to less rather than more protection of the victims.[152]

VI. Expert Evidence in Toxic Tort Cases

In most toxic tort cases faced by the Dutch courts, the experts remained virtually invisible; their reports were cited by the courts as proving one point or another, and few problems surfaced. One noticeable and interesting exception is the Halcion case cited above. This case casts some light on how Dutch courts deal with expert evidence in toxic tort cases, and particularly what happens when one of the parties criticizes the expert.

After the Court of Cassation determined what constitutes a defective product, it remanded the case to the Court of Ap-

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(1993); J. Hijma, *DES-dochters*, ARS AEQUI 123, 130-31 (1993); C.J.M. Klaassen & A.A. van Rossum, *Des-tijd(s), en hoe nu verder?* RM-THEMIS 4 (1994); J. SPIER, DE DES-DOCHTERS NTBR 195 (1992). *But see* J.M. van Dunné, DES-DOCHTERS TMA 15 (1993-1) (arguing that although it might be case that culprit does not have any part in damage done, it is clear that victims are even less to blame). *See also* N. Frenk, *Toerekening naar kansbepaling*, 13 NEDERLANDS JURISTENBLAD 482, 487-88 (1995); Ingelse, *supra* note 145, at 1409. In similar vein, but written much earlier, is J.H. Nieuwenhuis, *Alternatieve causaliteit en aansprakelijkheid naar marktaandeel*, PREADVIES VERENIGING VOOR BURGERLIJK RECHT 15-16 (1987).

[151] Note that the DES courts did *not* decide — and still have not decided — whether the pharmaceutical companies in fact acted unlawfully by manufacturing and distributing DES because of its alleged health effects or for failure to warn against those dangers. The decision of the Court of Cassation solely concerned the issue of who could be held to pay damages if and when a causal relation is established. The question of whether the drug DES was defective in light of the standard adopted by the Court of Cassation in *Halcion I*, HR 20 june 1989, NJ 1990, 652, thus is still open.

[152] *See* Dommering-van Rongen, *supra* note 150, at 282; SPIER, *supra* note 150, at 196.

peals.[153] The appellate court appointed experts on proposal of the parties, and asked the experts to investigate the damage suffered by each of the twenty-six plaintiffs. In the exercise of this duty, the experts interviewed the victims and other relevant persons. The defendant Upjohn, however, was unable to attend all interviews. Upon completing their task, the experts filed their report with the court. That report contained no references to relevant literature on the subject, and omitted some of the essential underlying factual data that led the experts to their findings. Throughout the trial, this data remained undisclosed to the Court of Appeals and the manufacturer, or so it appears from the case report. In response to criticism by the defendant, the court decided that (a) it was sufficient that the parties were able to comment upon a draft report of the experts, and that the experts took account of these comments in drafting the final version; (b) the experts did not fail in performing their task by not referring to relevant literature; and (c) the contents of the interviews held by the experts were sufficiently recorded in their report. It subsequently adopted the experts' conclusions.

On appeal to the Court of Cassation, Upjohn argued that the Court of Appeals erred on four points of law in holding that (a) the experts needed not honor each and every request on part of Upjohn to be informed of their findings; (b) the experts need not refer to literature; (c) the contents of the interviews need not be recorded more extensively than was done in this case; and (d) that the report could be used in evidence without disclose of the essential underlying data. The Court of Cassation, however, did not find fault with the decision of the Court of Appeals.

In rejecting the argument that experts are obliged to follow requests for information, the Court noted that the experts feared that consenting to the requests of Upjohn would infringe their impartiality, and that the appellate court apparently believed this fear was not completely groundless. Second, the Court noted that the argument that experts must refer to relevant literature cannot be accepted. Whether experts should refer to literature depends on the circumstances of the case. In ruling that the experts did not fail their duty, the appellate court took

[153] *See* HR 20 sept. 1996, NJB 1996, nr. 178C (describing case on remand).

account of the fact that the experts were extremely qualified and had been appointed on mutual agreement of the parties. This motivation, the Court of Cassation held, was correct. In response to the third allegation, the court stated that the principle of "*audi et alteram partem*"[154] does not require that a party, not present at the interviews conducted by the experts, have the opportunity to independently assess the complete contents of such interviews. Lastly, the Court of Cassation stated that although it is true that the manufacturer would have had the right to question the experts had they been called to testify as "party-witnesses," the same rule does not apply to experts not called to testify. The Court of Cassation held that expert evidence has its own statutory regulation, and there is therefore no reason to analogically apply to experts the rules for witnesses.

The Court's holdings indicate the dominant position of the expert under Dutch law; both culturally and institutionally. The expert is primarily an assistant to the court. Historically, expertise and experts have been regarded in terms of neutrality and impartiality; assumptions that hold, even in the face of substantial criticism regarding the exercise of their duties. Equally important is the fact that the appellate court in Halcion, much like courts in other complex civil cases involving expert evidence, appointed a plurality of experts, who subsequently prepared a joint report. In the Dutch legal system, experts are expected to solve disagreements among themselves and not bring them into the open. The joint report that follows their negotiation catches two flies at once: it legitimizes reliance upon experts in light of the perceived impartiality and neutrality of their arguments, and it prevents potential conflicts from disrupting the proceedings. Although this may be considered beneficial in some cases, in others its effects may be less fortunate.

VII. TOXIC TORT IN HOLLAND

In the struggle with asbestos, Halcion, and DES, the Dutch courts clearly have allocated the burden of society's uncertainty regarding the actual tortfeasor, and to a lesser degree scientific uncertainty, on the side of the most financially solvent party. In

[154] Both parties have a right to be heard by the court.

both the asbestos cases and the DES case, the Court of Cassation went to some length to shift the burdens of proof — actually, the risk of not being able to prove essential facts — on the employer or manufacturers. Indeed, under the DES decision, producers can be found liable for more damage than they actually caused or could have caused; an outcome that some consider completely justified in light of the less attractive alternative of burdening the victims with the consequences of uncertainty. Others, however, argue that this burden-shifting is neither acceptable nor harmless.[155]

The Dutch courts' attitude displayed in toxic tort cases may be attributable to the fact that the Dutch courts have not yet faced "hard" toxic tort cases; cases in which the state of the art has not reached any level of clarity. Indeed, there is little doubt that this is at least part of the explanation for the contrast between the United States and the Netherlands. Yet, the one case dealing with Halcion, the substance that Sanders[156] put on par with Bendectin and silicone breast implants for the scientific uncertainty that surrounds it, indicates that something else is happening. Not only is there no decision or rule addressing the scientific evidence that may be used to prove causation, but the courts appear to take much of the scientific evidence presented to them for granted. The court appoints the experts, requests additional information, and decides the case. Throughout this process, the experts' evidence remains undemanding, unproblematic, and quite acceptable, even in the face of allegations that the experts failed to report the most salient details. In the Halcion case, the Court of Appeals more or less held that the failure of the experts to disclose to the court or the parties the essential underlying data that led them to their findings (both the scientific basis of the conclusion and the facts of the case) did not amount to a violation of law.

Some may argue that Halcion was just an unfortunate case. However, research conducted on the use of expert evidence by the Dutch courts in other areas appears to indicate that Halcion is not an accident.[157] The problem with the Dutch lies in the

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[155] *See* Bolt & Spier, *supra* note 104 (analyzing tort law in Netherlands).

[156] *See supra* note 32 and accompanying text.

[157] On experts in criminal cases, and the tendency among judges to accept the expert's

fact that we tend to compromise and pacify rather than argue and intensify potential conflicts.

Some years ago, the American evidence professor Terry Anderson from Miami participated in a research group at the Netherlands Institute for Advanced Study (NIAS) at Wassenaar (Zuid-Holland). Having already been exposed to the Dutch court culture for a couple of months, Anderson was still puzzled by the cursory attention Dutch judges give to matters of scientific evidence. In his efforts to better understand the Dutch, Anderson once watched Judge Nijboer prepare court cases from the files in his study. At the end of the session Anderson asked why many files were dealt with so briefly. The answer he got was "I'm just checking." A couple of days later, the NIAS group was playing ping-pong during a lunch break. Anderson's team faced its defeat by a score of twenty to nine. Anderson's partner, a Dutch scholar, proposed to give up, to which Anderson responded with *"That's the problem with you Dutch, you give up too easily. You don't even try."* As the reader has been able to judge, there is much truth in his argument.

Although the "don't try movement" does have its own blessings, it is also a potentially dangerous development, both for toxic tort cases and for expert evidence itself. With respect to toxic tort cases, shifting the burden of proof to employers and producers impedes the law's preventative function. Whether manufacturers or distributors actually behaved in violation of their duty of care is no longer relevant, and neither, necessarily,

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opinion at face value, see Petrà van Kampen, *Deskundigen in Nederlandse strafzaken. Wie maar één klok hoort, hoort maar één toon*, MODUS 19 (1996). For case law confirming this argument, at least in criminal cases, see, e.g., Hof Amsterdam, 30 Dec. 1992 (*Haarlemse stoeptegelmoord*) (unpublished manuscript, on file with author), in which the court accepted the opinion of state psychiatrists. The court concluded that "now the experts disagree, the court gives decisive weight to the special expertise of the Psychiatric State Hospital in examining the mental disabilities of persons suspected of violent crimes." *See also* HR 26 sept. 1995, DD 96.037 (explaining how Court of Cassation saw nothing wrong with appellate court's acceptance of practitioner's statement that his investigation led him to believe that father had sexually abused two daughters without reference as to what investigation entailed); Rechtbank's Gravenhage, 13 Oct. 1995 (*balpen 'moord'*) (describing how District Court of The Hague convicted young man to 12 years for murdering mother with cross-bow and ball-point on basis of testimony of his former psychologist, despite fact that many experts consulted throughout investigation argued that it cannot be done). The appellate court overturned the conviction on April 4, 1996.

is the fact that the defendant producer did not commit any wrongs while bringing a product onto the market. Having lost some forms of collective risk-sharing within the social security system, the Dutch have reinstalled collective responsibility on a legal level.[158] Meanwhile, many see a time bomb waiting to explode. The question that keeps us all quite busy is: will it?[159]

VIII. *DAUBERT* IN THE LOWLANDS

That leaves the question: what would we do if Bendectin litigation came to visit the Lowlands? What would happen if the drug Bendectin was manufactured and distributed by Orange Pharmaceuticals B.V., registered by the Dutch governmental health agency responsible, taken by hundreds of thousands of pregnant women, and a considerable number of children born out of these pregnancies had limb reduction birth defects? We are not sure about what *would* happen; we do have our own — modest — opinion, however, on what *should* happen.

First of all, it is very likely that affected persons would join forces and organize their interests. They would gather all available and relevant information regarding the subject. So far, nothing new. Without filing any official complaints or lawsuits, the representatives of the organization, probably together with some attorneys from private law firms, would seek contact with the producer and the insurance companies involved, in order to settle the issue and to prevent formal legal steps from being taken. It is not inconceivable that a settlement could be reached, nor that this settlement would involve the State.

Should the parties fail to reach a settlement, then the organization, or individuals with support of the organization, might

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[158] *See* A.J. Van, *Collectieve verantwoordelijkheid in het civiele aansprakelijkheidsrecht*, R&R 1993; Van der Velden, *supra* note 26.

[159] *See* Faure et al., *supra* note 128 (concluding that ongoing increase in number of claims and damages awarded can be expected in future). They do not, however, expect a crisis, mainly since the three factors they identify as potentially causing that effect — contingency fees, severely restricting the social security system, and punitive damages or damages for psychological damage — are not likely to manifest themselves in the Netherlands. *See id.* at 85-86; *see also* Bolt & Spier, *supra* note 104, at 385 (concluding that problems are to be expected for some areas of law). For occupational diseases, Bolt and Spier argue that one should not be too surprised if such would lead to an explosion of claims. *See id.* Both reports addressed the implications of these perceived trends for insurance companies.

take legal steps. The plaintiffs would bring the claim before the District Court of Amsterdam, where it would probably be investigated by an investigating judge (*rechter-commissaris*) on the proposal of one or both parties. The task of the investigating judge would be to hear witnesses, including victims, and to appoint experts.[160] These experts would either produce a joint report, or individual reports. Should the latter be the case, the experts would be aware of the findings and opinions of their colleagues. Independent of the actions of the investigating judge, the parties might retain their own experts to provide their thoughts on the matter.

Confronted with the claim, the District Court would probably ask the plaintiffs to produce what is called a beginning of proof: proof that Bendectin is *likely* to be the factor that causes the limb reduction birth defects at issue. The plaintiffs may show that this is the case, for example, by producing experts' studies on the cause of limb reductions birth defects — in vivo/in vitro studies *and* epidemiological studies. This type of expert evidence was not admissible in the original *Daubert* case, because it did not meet the standard of admissibility for scientific evidence. If the plaintiff succeeded and the court considered it more likely than not that Bendectin did in fact cause the damage suffered, the court would accept the "beginning of proof" and shift the burden of proof to the defendant. The defendant would then be required to show that it took all neccessary precautions in light of the state of knowledge at that point in time. If the defendant failed, it would be held liable.

The evidence on Bendectin, however, is quite weak. As Sanders indicated in 1993, "no [epidemiological; PvK/HN] study found a significant relationship between Bendectin usage and limb reduction defects."[161] Additionally, in the *Daubert* remand opinion, Judge Kozinski argued that "none of the plaintiffs' epidemiological experts claims that ingestion of Bendectin during pregnancy more than doubles the risk of birth defects."[162]

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[160] In this context, it should be noted that the appointment of experts in such a complex case does not need to be requested by one or both parties. The investigating judge, like the trial judge, is free to appoint experts at his own motion, should he consider it necessary. In a case like this, he would probably do so.

[161] Sanders, *supra* note 5, at 24.

[162] Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1320-21 (9th Cir. 1995).

Different from DES, asbestos, and even Halcion (at least if administered in heavy doses), there is no evidence clearly indicating a causal relationship between Bendectin and limb reduction birth defects. Given this absence of evidence, we believe there is no reason for the court to shift the burden of proof to the defendant under the proposition that it might be responsible. As Van der Velden has conclusively argued elsewhere, if the court would sever the link between factual causation and liability on the basis of mere indications — in this case, indications that Bendectin might produce limb reduction defects in some cases — then tort law has gone too far,[163] even by Dutch standards.

Most likely, the plaintiffs would appeal this decision to the Court of Appeals in Amsterdam, where it would be heard by a panel of three judges. This court would then decide the question anew. If we were that court, we would decide of the case along the following lines:

Gerechtshof te Amsterdam
COURT OF APPEALS OF AMSTERDAM
Second Chamber for Civil Cases

Arrest[164] of January 31, 1997 in the case ('97-113) of:
DONALD DUTCH DAUBERT,
born June 22, 1966, who has chosen domicilie[165] at the office of his *advocaat*[166] Mrs. P.T.C. van Kampen,
Herengracht 48, NL-2312 LE Leiden,
appellant;
Procureur at the Court in Amsterdam: Mr. J.E. van der Bilt;

AGAINST

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[163] *See* Van der Velden, *supra* note 26, at 34-36.

[164] An *arrest* is a decision of a higher court (Court of Appeals or Court of Cassation). *Vonnis*, by contrast, is a term used for a decision by a lower court (court of limited jurisdiction or District Court).

[165] In civil cases, the parties usually need to be represented by a professional lawyer (someone who is "*advocaat en procureur*").

[166] Lawyer, attorney at law.

ORANJE PHARMACEUTICS NEDERLAND BV,[167]
established at and legally settled in Amsterdam,
Keizersgracht 406-II, NL-1016 GC,
geïntimeerde,
Procureur at the Court in Amsterdam: Mr. F.D. Roosevelt Jr.

1. The *Vonnis* of the District Court of Amsterdam

In 1990, plaintiff (now appellant) Daubert filed a case at the registers office at the District Court of Amsterdam, contending that the limb reduction birth defects he suffers were caused by drug consumption during pregnancy by his mother. The drug involved was Bendectin, an anti-nausea drug licensed by the responsible State agency. This drug was produced and distributed by defendant, Oranje Pharmaceutics Nederland BV from 1957 to 1982.[168] It was available on prescription only and taken by many pregnant women during the period mentioned above. The legal basis of the claim was founded on article 6:162 BW.[169]

Under the authority of the investigating judge in charge of civil cases, and with approval of the parties, three experts were appointed to investigate the possible connection between the consumption of Bendectin by the mothers and the injuries suffered by their offspring. The experts produced a joint report. Based on their analysis of in vitro and in vivo animal studies, chemical structures analysis, and a reanalysis of epidemiological studies, these experts concluded that a statistically significant correlation between the drug and the effects mentioned could

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[167] *Besloten Vennootschap*, refers to a company with limited liability. Different than many *Naamloze Vennootschappen* (NV), the shares of such a company are in the hands of a few people and not subject to trade on the stock exchange market.

[168] In 1983, the license was withdrawn, following many complaints to the Ministry of Public Health.

[169] Article 6:612 BW contains the general provision that a tortfeasor is liable for the damages caused by his unlawful conduct or negligent behavior. The current regime of product liability rules is to be found in articles 6:185 BW ff. The reason why plaintiff Daubert did not invoke them in this case is that they became effective in 1992, while the suit was filed in 1990.

not be established. However, the experts did find individual medical case studies suggesting that Bendectin might be a teratogen.[170] In 1983, these case studies led the Minister of Public Health to withdraw the distribution license.

The Court tried the case during three sessions in 1991-1993. Plaintiff (now appellant) contested the experts' report during the trial sessions. In its *vonnis* of 17 November 1993, the District Court of Amsterdam denied appellant's claim for damages. The Court found that plaintiff (now appellant) did not meet his burden of proof; appellant could not show by a preponderance of evidence that the injuries from which he suffers were indeed caused by the product Oranje Pharmaceutics Nederland BV manufactured and distributed.

2. The Case on Appeal

Appellant filed his appeal on November 20, 1993 at the register's office at the District Court. In May 1995, the case was placed on the *rol*.[171] In his *memorie van grieven*,[172] appellant argues that the District Court of Amsterdam erred in denying his claim: 1. the court wrongfully determined that plaintiff needed to carry a full burden of proof of causation instead of accepting the 'beginning of proof' he could offer by presenting the court with reports on the case studies mentioned above; and 2. the court, after accepting this beginning of proof, should have shifted the burden of proving the absence of causation to Oranje Pharmaceutics Nederland BV. Plaintiff refers to the decision of the *Hoge Raad der Nederlanden* of 9 october 1992 in the case of DES dochters versus Bayer c.s. (published as Nederlandse Jurisprudentie 1994, 535).

Article 177 Code of Civil Procedure offers the court the possibility to put the onus probandi upon the defendant, when such is appropriate for reasons of fairness.

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[170] A teratogen is a substance that causes birth defects.

[171] After filing a civil case, it not "automatically" put on the schedule of one of the chambers. How to proceed depends on the policy of the particular plaintiff or on both parties. Of course, this is different in bankruptcy cases or divorce cases, where a public order interest is present.

[172] A memorandum containing the points on which the appellant disagrees with the *vonnis*.

3. The Facts of the Case

Between the parties it is *in confesso* (not disputed) that 1. Donald Daubert suffers from limb reduction birth defects; 2. his mother took Bendectin during pregnancy (1965-1966); 3. Oranje Pharmaceutics Nederland BV was the sole manufacturer and distributor of Bendectin; 4. Bendectin was removed from the market in 1983, as a consequence of the decision by the Minister of Public Health to withdraw the license for distribution to and sale (by prescription only) in pharmacies within the Netherlands.

4. The Findings of the Court of Appeals

4.1. Donald Dutch Daubert claims damages on the basis of article 6:162 BW. For the purpose of this appeal, the court will assume for the moment that Bendectin is a defective product.[173] The question that faces us in in this case is whether it can be established on the preponderance of probabilities that Daubert's birth defects were *caused* by the product Oranje Pharmaceutics Nederland BV manufactured.[174] The major issue in this case is thus the proof of causation. If causation could be proven, Oranje Pharmaceutics Nederland BV should be held liable for the damages, unless Oranje could prove that it took all reasonable measures in order to prevent negative health effects or warned sufficiently against known side effects at the time.

4.2. In this case, the basic problem is that there is no data available from representative experimental studies among humans, directly involving the physical effects of the drug on consumers and their offspring. The epidemiological studies available give no clear answer to the determination of correlations, as was

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[173] See the definition of "defective product" in Halcion case, HR 30 june 1989, NJ 1990, 652 (stating that product is defective when it does not possess safety one is allowed to expect from it).

[174] Although it would be logical to start with the question of whether Bendectin should be considered a defective product before asking the question of whether it caused the alleged effects, it is more efficient to answer the second question first. After all, when a causal relation between the drug and the alleged effects cannot be established, the claim necessarily has to fail. The Court of Cassation followed a similar line of argument in the DES case, HR 9 oct. 1992, NJ 1994, 535.

found by the experts. Furthermore, an evaluation of the medical case studies mentioned above indicates that it is highly improbable that new studies can and will be undertaken in the near future.

4.3. Plaintiff (now appellant) argues that the burden of proof should be allocated to the side of the *geïntimideerde*, referring to the DES dochters decision, mentioned above. This argument cannot be accepted. In the DES dochters case, the probandum involved an identification problem with regard to the plurality of producers. In that case, the Court of Cassation found it a matter of fairness — should the DES dochters meet their burden of proof on the issue of causation — that, with a view to article 6:99 BW, each of the individual producers was held liable for the damages, unless it could show that it could not have been its product that a particular mother consumed. In the present case, the issue of a plurality of producers/distributors in relation to alternative causation as regulated in article 6:99 BW was never raised. It is not even an issue, since it is clear and undisputed that Oranje Pharmaceutics was the sole producer and distributor of the drug.

4.4. The Court of Appeals furthermore wants to point out that in the actual case three independent experts, appointed by the investigating judge in the District Court of Amsterdam, evaluated the available scientific data. The experts were appointed with consent of both parties. The experts concluded that no significant correlation was found between the use of Bendectin and the birth defects mentioned above. The Court holds that there is no reason to believe that either Donald Dutch Daubert or Oranje Pharmaceutics Nederland BV can come up with new scientific evidence that might throw new light on the issue of causation. Considering this given state of affairs, it would not be a matter of fairness to impose a burden of proof — the risk of not being able to prove[175] — in relation to the probandum "the absence of causation" to Oranje Pharmaceutics Nederland BV. Considering that Daubert did not meet his burden of proof on the presence of causation, the District Court was justified in denying the claim.

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[175] *See generally* R.H. GASKINS, BURDENS OF PROOF IN MODERN DISCOURSE (1992).

5. Obiter Dictum

5.1. A next question arising is whether Oranje Pharmaceutics Nederland BV was negligent (for lack of due care) because it did not provide consumer information on possible side-effects at the time Daubert's mother consumed the drug. It is the Court's opinion that this is not the case. The first medical case studies suggesting causation of birth limb reduction by Bendectin consumption were published in 1967, after Daubert was born. Therefore, Oranje Pharmaceutics Nederland BV cannot be held responsible for reasons of foreseeability of the defects mentioned before, without mentioning them to the consumers.

5.2. In this context, it is relevant that Oranje Pharmaceutics BV did show to the government that sufficient tests were done — with a view to the standards of that time — in the fifties, at the time of the application procedure for the distribution license.

6. Decision

The Court of Appeals:

- affirms the *vonnis* of the District Court of Amsterdam of 17 November 1993;
- orders Daubert to pay the costs and expenses of the appeal to Oranje Pharmaceutics Nederland BV (Dfl. 7.400).

This *arrest* was issued by the Justices van Dijck, Stuyvesant, and Nijboer,[176] in the presence of Mr. van Zwieten, clerk. The *arrest* was read out in public, during a special session of the Court in Davis, California, on Friday, January 31, 1997.

Signed:

J. van Dijck P. Stuyvesant
L.J.A. van Zwieten J.F. Nijboer

[176] The court is not allowed to disclose that Justice Nijboer delivered the opinion of the Court by drafting this verdict, because of the *statutory* confidentiality of the deliberations in court-panels (secrecy of Chambers).