



BERGESON & CAMPBELL, P.C.

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**Genomics and the Evolution of Tort Liability**

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**ABSTRACT**

**This presentation will discuss the evolving relationship among genomics, epigenetics, and toxic torts. This toxicogenomic concept links exposure, biomarkers and gene expression, and the probability of disease as a means to recover damages or defend a products liability challenge. This presentation surveys toxic tort theories of liability and actionable harm, state and federal conflicts in the role of scientific evidence and issues of proof in the courtroom, and the emerging genomic and epigenetic discoveries that identify cause and effect, exposure, and result.**

**TOXIC TORT CLAIMS**

**Products Liability: Causes of Action and Claims**

**Tort**

Failure to warn  
Trespass (bodily)  
Strict liability under Restatement of Torts 402 A  
Ultrahazardous activity  
Defective design (whether the product is unreasonably dangerous as tested by a consumer's expectations)  
Defective manufacturing  
Negligence *per se*  
Negligent infliction of emotional distress  
Negligent misrepresentation  
Wrongful death  
Unfair or deceptive trade practices (in tort, as, for example, provided in the "Texas Deceptive Trade Practices Act")  
Negligent testing (failure to test product; failure to test and then warn genomic subpopulations)



### **Contract**

Breach of express warranty  
Breach of implied warranty of merchantability  
Breach of warranty of fitness for particular purpose  
Unfair or deceptive trade practices

### **Causation/Evidence Standards**

#### **Federal Courts**

Federal Rules of Evidence 702 provides in all federal court cases that the court is a gatekeeper to admit only reliable evidence as to causation; that is, the evidence must be reliable, peer reviewed, replicable, whether the method has a known potential rate of error, and more than merely generally accepted in the relevant community of scientists.

“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, provided that (1) the testimony is sufficiently based upon reliable facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.”

#### **State Courts**

State standards mostly have adopted and maintained the Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), test for admissibility of scientific evidence; that is, an expert’s testimony may be admitted to prove causation if the theory or method which is the subject of the testimony has gained general acceptance in the relevant scientific community. This admissibility standard of evidence permits a toxic tort plaintiff to get to the jury on a doctor’s testimony that the injury or disease was caused more likely than not by exposure to the chemical or substance.

### **CASES**

Arnold v. Dow Chemical Company, 110 Cal. Rptr. 2d 722, Court of Appeal, Second District, Division 2, California, August 14, 2001. Alleged exposure to dursban (organophosphate insecticide) by minors, one in utero. Held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not foreclose state common law causes of action. Pleading in strict liability, breach of implied warranties of fitness, and merchantability survive. As a matter of public policy, injury by pesticides to be borne by manufacturers and distributors. Privity not required or necessary. A consumer need not be a purchaser.



Bockrath v. Aldrich Chemical Co., 980 P.2d 298, Supreme Court of California, July 29, 1999. Plaintiff sued 55 defendant chemical manufacturers for workplace exposure. Sets pleading standards for chemical exposure and injury; the plaintiff must prove that the defective products were a substantial factor as test for causation of injury. “. . . [a] very minor force that does harm is a substantial factor.”

Cassidy v. Smithkline Beecham Corporation, Pa. Ct. of Common Pleas, Chester County, No. 99-10423, filed December 14, 1999. Settled July 1, 2003. Class action filed on behalf of a subpopulation of individuals with gene type HLA-DR4+ who had been given the LYMERix lyme disease vaccine and who may have been at risk of developing arthritis. LYMERix withdrawn from market, SKB to pay \$975,000 fees and \$147,000 costs to plaintiffs’ lawyers, and plaintiffs did not relinquish potential personal injury and economic damage claims. No class plaintiff demonstrated any injury from the vaccine.

John Castillo, et al., v. E.I. Du Pont, et al., No. SC00-490. Supreme Court of Florida. Opinion filed July 10, 2003. Rehearing Denied September 4, 2003. Held: that the expert testimony offered by the Castillos at trial was admissible under Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). This case involves a products liability and negligence claim against E.I. Du Pont de Nemours & Co., Inc. (DuPont), the registrant of Benlate, and Pine Island Farms, Inc. (Pine Island), the owners of a “u-pick” farm which used Benlate and operated in the petitioners’ neighborhood. Donna and John Castillo alleged that when Mrs. Castillo was seven weeks pregnant, she was exposed to Benlate, an agricultural fungicide used by Pine Island. They further alleged that benomyl, the active ingredient in Benlate, entered her bloodstream and caused microphthalmia, a rare birth defect involving severely underdeveloped eyes in her unborn son.

Daubert v. Merrill Dow Pharmaceuticals, Inc., 951 F. 2d 1128 (9th Cir. 1991). Plaintiffs Jason Daubert and Eric Schuller suffer from limb reduction birth defects. They alleged that these defects resulted from the fact that their mothers used Bendectin, a prescription anti-nausea drug, during pregnancy.

Daubert v. Merrill Dow Pharmaceuticals, Inc., 43 F. 3d 1311 (9th Cir. 1995). On remand from the United States Supreme Court, the Court stated their instructions regarding admissible testimony to ensure that “an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.” Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2799, 125 L.Ed.2d 469 (1993).

Delhite v. United States, 346 U.S. 15, 53 (1953). Action against the United States to recover damages for death resulting from the explosion of ammonium nitrate fertilizer produced under the control of the United States. U.S. District Court’s analysis of the specific aspects of the manufacture was foreshadowed by a theory of foreseeability of the risk: “This record discloses blunders, mistakes, and acts of negligence, both of omission and commission, on the part of Defendant, its agents, servants, and employees, in deciding to begin the manufacture of this inherently dangerous Fertilizer.”



Dillon v. United Horticultural Supply and Zeneca Corp., 42 P.3d 598, Arizona Court of Appeals, Division 2, February 26, 2002. Complaint for personal injury from exposure to herbicide, based on breach of express warranty, fraudulent misrepresentation, and strict products liability. Court held that salesman's statements were consistent with label and that claims were FIFRA preempted and therefore not breach of express warranty.

Greenman v. Yuba Power Products, Inc., 377 P.2d 897, Supreme Court of California, 1963. A manufacturer placing a product in the stream of commerce has a legal duty to prevent defects causing injury.

Jenkins v. Platte Chemical Company, et al. Supreme Court of Kansas (1994) 886 P.2d 869. Complaint in products liability, design defect that 2, 4-D caused farmer/plaintiff's multiple myeloma cancer. Court held that FIFRA preempted some claims and that consumer could not prevail on strict liability design defect claim without identifying what aspect of the manufacturers' product was defectively designed.

Leach v DuPont, Wood County Circuit Court, West Virginia, Civil Action No. 01-C-608. Summary judgment decision April 29, 2003. On appeal to the West Virginia Supreme Court of Appeals. Class action products liability suit for water contamination with perfluorooctanoic acid (PFOA/C-8): (1) potential liability for thousands of claimants, (2) medical monitoring, (3) ground and surface water contamination from chemical production facility, and (4) allegation of document destruction and failure to keep adequate records.

1. EPIDEMIOLOGICAL STUDIES HAVE NOT EXAMINED DEVELOPMENTAL OUTCOMES.
2. NO STATISTICALLY SIGNIFICANT ASSOCIATION BETWEEN EXPOSURE AND PROSTATE CANCER.
3. INCREASE IN ESTRADIOL LEVELS IN WORKERS WITH THE HIGHEST PFOA SERUM LEVELS, BUT NO ADVESE EFFECTS OBSERVED.
4. NO SIGNIFICANT DIFFERENCES AMONG WORKERS WITH DIFFERENT EXPOSURE LEVELS.
5. NO OBSERVED DEVELOPMENTAL TOXICITY AFTER ORAL EXPOSURE TO VERY HIGH DOSES IN RATS.
6. TRIAL JUDGE, WITH NO TRIAL, NO EVIDENCE, NO EXPERT TESTIMONY, RULES AGAINST DUPONT. UP TO 50,000 PERSONS TO BE MEDICALLY MONITORED IN THE CLASS ACTION. WITH INCOMPLETE, INCONCLUSIVE EPIDEMIOLOGY, DUPONT MAY HAVE TO PAY FOR THE MEDICAL MONITORING FOR YEARS AT A FEW THOUSAND DOLLARS PER YEAR PER PERSON.



Netland v. Hess and Clark, Inc., 284 F.3d 895, U.S. Court of Appeals for the Eighth Circuit, March 26, 2002. Rehearing *en banc* denied, May 13, 2002. Upholding FIFRA preemption summary judgment decision of U.S. District Court for Minnesota in favor of manufacturer. Complaint that insecticide (DDVP) caused plaintiff's aplastic anemia. Pleading in design defect, ultra hazardous activity, negligence, and failure to warn. Clear failure by plaintiff to read and follow label instruction. Federal District Court was given the opportunity and option of ruling for defendant based on exclusion of expert opinion.

People v. Kelly 17 Cal. 3d 21 (1976) and People v. Leahy 8 Cal. 4th 587 (1994) expressly rejecting Daubert in favor of Frye standard of expert testimony admissibility.

Sleath v. West Mont Home, 16 P.2d 1042, Supreme Court of Montana, December 28, 2000. Failure to warn claims in negligence, strict liability, and breach of express warranty not preempted by FIFRA. "Congress did not intend to extinguish common law remedies or actions for damages." Complaint for personal injury as a result of alleged exposure to dursban. The claim and lawsuit were permitted to go forward.

Turner v. Chevron Corporation, et al., Superior Court, State of California, County of Los Angeles, Case No. BC256293. Filed August 16, 2001. Complaint by CalTrans worker for personal injury as a result of exposure to pesticides over a 20 year period. Complaint identifies 92 products, 56 active ingredients, produced by 42 different manufacturers, and sold by 15 different distributors. Complaint in strict liability -- design defect, negligence, breach of implied warranties, battery, and loss of consortium.

#### ARTICLES AND TREATISES

Uniform Commercial Code § 2-318, "Third Party Beneficiaries of Warranties Express or Implied." "Alternative C" : A seller's warranty whether express or implied extends to any person who may reasonably be expected to use, consume, or be affected by the goods and who is injured by the breach of the warranty. **A seller may not exclude or limit the operation of this section with respect to injury to the person of an individual to whom the warranty extends.**

Restatement of the Law Second. American Law Institute, 1964. Torts, Products Liability 2(b):

" . . . a product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe . . . ."

Restatement of the Law Second. Torts: § 402A. The American Law Institute. "Special Liability of Seller of Product for Physical Harm to User or Consumer." This marked for the first time the Institute's recognition of the privity-free strict liability for sellers of defective products. Emphasis was to eliminate privity so that a user or consumer, without first having to establish negligence, could bring an action against a manufacturer, as well as against any other member of a distribution chain that had sold a product with inadequate warnings.



Restatement of the Law Second. Torts: § 402A, comment j. The American Law Institute. “Where a warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such warning which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.” Restatement of the Law Third. Torts: § 2, comment 1 expressly rejects the Restatement Second warnings approach: “When an alternative design to avoid risks cannot be unreasonably implemented, adequate instructions will normally be sufficient to render the product reasonably safe.”

Federal Judicial Center, Reference Manual on Scientific Evidence, 1994; Second Ed. 2000. West Group.

Toxicology, epidemiology, survey research, statistics, multiple regression, economic losses, and damages. Discussion of Daubert v. Merrel Dow Pharmaceuticals, Inc., standards of admissibility and reliability of scientific evidence and expert opinions. Daubert and progeny specified in Federal Rules of Evidence, 702, Testimony by Experts.

“Causality in Epidemiology, Health Policy, and Law,” Environmental Law Reporter, 27 ELR 10279, June 1997.

Gary E. Marchant, “Genetic Susceptibility and Biomarkers in Toxic Tort Litigation,” 41 Jurimetrics 67 (2000).

Susan R. Poulter, “Genetic Testing in Toxic Injury Litigation: The Path To Certainty or a Blind Alley?,” 41 Jurimetrics 211 (2001).

“Code of Medical Ethics,” Council on Ethical and Judicial Affairs, American Medical Association, 1998. Section 9.07. Discussion of a physician’s ethical duties when testifying in a legal matter: limit testimony to sphere of medical expertise.

Neurotoxicology: A Clinical Sourcebook. P. Bernad. Lexis Law Publishing. 1998.

“Epidemiologic Proof in Toxic Tort Litigation,” Black and Lilienfield, 52 Fordham Law Review 732, 1984.

Occupational and Environmental Neurology. Neil Rosenberg M.D. Butterworth-Heineman. 1995.

General and Applied Toxicology. Ed. by Ballantyne, Marrs, Turner. Stockton Publishing. 1995.

The Merck Manual of Diagnosis and Therapy. Seventeenth (Clinical) Edition. 1999.

Toxic Tort Litigation, Greer and Freedman, Prentice Hall, 1989.

Gary E. Marchant, “Genomics and Environmental Regulation. Scenarios and Implications.” Center for the Study of Law, Science and Technology, Arizona State University College of Law. January 2000.



## GLOSSARY

### **Epidemiology**

Epidemiology is evidence of an association of events that occur more frequently than would be expected by chance. Thus, epidemiological evidence of an association between exposure and disease, that are not merely temporal, is some statistical evidence of a causal relationship. Although epidemiology describes an association between a chemical or substance and a population, it alone does not prove causation, however.

### **Epigenetics**

The study of heritable changes in gene function that occur without a change in the DNA sequence. The study of mitotically and/or meiotically heritable changes in gene function that cannot be explained by changes in DNA sequence. Epigenetics attempts to describe the inheritance of information on the basis of gene expression, in contrast to genetics, which attempts to describe the inheritance of information on the basis of DNA sequence.

### **FIFRA Preemption**

In the case of pesticide exposure, at least in federal courts and most state courts, as a result of a pesticide and its label having been approved by the U.S. Environmental Protection Agency (EPA), plaintiffs' cases are routinely dismissed because federal law is supreme over state law claims, unless the complaint pleads defective design, defective manufacture, breach of express warranty, or negligent misrepresentation. All other challenges have been deemed to be attacks on the pesticide label and are preempted.

### **Genetic Variability (SNP)**

Single nucleotide polymorphisms constitute the majority of genetic differences among individuals and influence disease susceptibility and therapeutic response.

### **Polymorphism**

Thompson & Thompson, Genetics in Medicine, 6th ed. (at 87). Polymorphisms are not necessarily uncommon: “. . . different versions of a particular DNA sequence at one particular chromosomal location (**locus**) are called **alleles**. When alleles are so common that they are found in more than 1 percent of chromosomes in the general population, the alleles constitute what is known as genetic polymorphism. In contrast, alleles with frequencies of less than 1 percent are, by convention, called **rare variants**.”

### **Statutes of Limitations (SOL) and Latent Disease**

Limitation on time for filing a cause of action. Two years in most states, except California which has a one year SOL in negligence. Ohio, for example, has a four year SOL for asbestosis. Most states have adopted a discovery test for latent disease: once the plaintiff reasonably knows or should know that there is a suspected association between exposure to a substance and his disease, he has from that point until the term of the SOL to file a complaint. Thus, if a doctor suggests to the plaintiff a link, then that time starts the SOL.



## LEGISLATION

### SENATE BILL 1053

#### SUMMARY

7/31/2003 -- Reported to Senate, amended.

#### **Genetic Information Nondiscrimination Act of 2003.**

**Title I: Genetic Non-Discrimination in Health Insurance** -- (Sec. 101) Amends the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code to **prohibit health discrimination on the basis of genetic information or services. Defines genetic information as genetic tests of an individual or family member or occurrence of a disease or disorder in family members.** Such term shall not include information about the sex or age of an individual. Defines genetic services as genetic tests, genetic counseling, or genetic education.

(Sec. 104) Amends Title XVIII (Medicare) of the Social Security Act to prohibit an issuer of a Medicare supplemental policy from denying or conditioning the issuance or effectiveness of the policy, or from discriminating in the price of the policy, of an eligible individual based on genetic information, on the receipt of genetic services, or on a request for such services. **Prohibits the issuer of such a policy from requesting or requiring a beneficiary to undergo a genetic test.**

(Sec. 105) Applies the Health and Human Services medical privacy rules to the disclosure of genetic information. **Prohibits a group health plan, a health insurance issuer, or an issuer of Medicare supplemental policies from using or disclosing genetic information for purposes of underwriting, determining eligibility** to enroll, or premium rating. Prohibits such entities from using or disclosing genetic information for the creation, renewal, or replacement of a plan, contract, or coverage for health insurance or benefits. Prohibits such entities from requesting, requiring, or purchasing genetic information concerning a participant, beneficiary, or enrollee prior to the enrollment and in connection with such enrollment of such individual under the plan, coverage, or policy.

#### **Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information** --

(Sec. 202) Makes it **an unlawful employment** practice for an employer, employment agency, labor organization, or training program to discriminate against an individual or deprive such individual of employment opportunities **because of genetic information. Prohibits the collection of genetic information** except: (1) where health or genetic services are offered by the employer; (2) where an employer needs certain information to comply with the certification provisions of the Family and Medical Leave Act of 1993 or with State family and medical leave laws; (3) where an employer purchases documents that are commercially and publicly available that include family medical history; or (4) where necessary to monitor the effects of toxic substances in the workplace (when authorized by the employee or as required by law).



(Sec. 206) **Requires genetic information to be treated as part of an individual's confidential medical record, limiting disclosure** to certain parties, including the individual, the family, health researchers, or government officials investigating compliance with this title.