

SCOMM

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Representative Brian Porter

Dr. Leon Speroff

(W) (503) 494-4469

(H) (503) 621-3331

Cynthia Brooke, MD &
friend who is

#1 word Authg
on OB/GYNs.



Cynthia Brooke, MD
A balance of treatment
and prevention.

March 24, 1997

Post-it® Fax Note 7671		Date 3/27	# of pages 4
To TIM B		From Jim S.	
Co./Dept. Sen Kelly		Co.	
Phone #		Phone # 3727	
Fax # 3754		Fax #	

C.O.G
Gynecology

Senator Drue Pearce, Co-Chair of Senate Finance
716 West Fourth Avenue
Anchorage, Alaska 99501

Dear Senator Pearce,

I am OB-GYN in Anchorage, Alaska, and would like you to know of a grave situation which exists regarding medical research and our country's current legal system.

As an obstetrician and gynecologist, I have had occasion to interact with the court system, both as an observer and as a participant. Over the years, I think I have developed some insight into the interaction between medicine and the legal system. A great deal of problems seem to arise, and I think many of these problems result from the difference between science, medicine and the law. I think there is a definite problem in trying to solve scientific issues in the courtroom. To illustrate this point, I have a story to tell. I think this exemplifies what is wrong with our legal system today.

The story centers around a physician and scientific researcher named Dr. Marcia Angell. Dr. Angell is trained in internal medicine and is also the editor of *The New England Journal of Medicine*. Her job with *The New England Journal* is to evaluate the quality of studies and research submitted to the journal for publication. In this capacity, she had occasion to write an editorial in response to an article by Dr. David Kessler of the FDA who was considering declaring a ban on silicone breast implants. This ban was not going to be imposed, Dr. Kessler was carefully to say, because he thought they were unsafe, but only because he felt the company had an obligation to do more studies to prove they were safe. There have been rare cases of fatigue and other symptoms in women with these implants, but nothing significant had ever been reported in thirty years of use. Because of this, Dr. Angell told Dr. Kessler she did not think that the ban was a good idea. One million women at that time had breast implants, and she felt they would be unnecessarily alarmed. Again, these implants had been used for thirty years without any significant problems. Apparently Dr. Kessler wavered, but then he decided to go ahead and implement the ban on the implants. Unfortunately, the fact that Dr. Kessler said the implants were not unsafe did not make it through to the media or public at large. Women panicked. Lawsuits against Merrell-Dow burgeoned into the thousands. One jury verdict alone, in Houston, was for \$25 million. The average out-of-court settlement was \$1 million. Eventually Merrell-Dow, in desperation, settled the largest class action lawsuit in the history of the world at \$4.25 billion.

Two months after the settlement, the Mayo Clinic published the first rigorous study regarding breast implants and disease. This study found absolutely no association between disease and breast implants. This study was submitted to *The New England Journal of Medicine* for publication and was published on June 16, 1994. In that same publication, Dr. Angell wrote her second editorial on the subject. Like a good scientist, she pointed out the backwards sequence of events, in that first there was public opinion and then a ban and then lawsuits and then a huge class action settlement. Only after all this, was any evidence presented. This peculiar change of events, Dr. Angell dared to say, was due to some peculiar characteristics of the tort

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system in the United States of America which differs from any other tort system in the civilized world.

These differences include contingency fees of lawyers, which encourage a sort of lottery system where lawyers can build a case, then find clients to suit their case. For example, there are currently cases being built against Norplant which has a silicone base in penile implants. This is in spite of the Mayo Clinic study.

The second difference in the United States tort system is that the defendant pays no matter who wins. In Britain, Australia, Sweden, Canada, and the rest of the civilized world, loser pays. In the United States, Merrell-Dow was faced with a situation where even if they won every case, they would still have to pay out about \$200 million. This system encourages out-of-court settlements which are not justified by the facts or the evidence.

Also unique to our tort system in this country is the lack of scientific evidence presented to the jury. Expert witnesses are called to give biased testimony - in fact, that is their job! Judges often do not utilize the option to call neutral scientific witnesses to help them decide the issues based on the evidence, although this option is available to them. In addition, in Alaska we have an expert advisory panel which is sometimes utilized and sometimes not. In many cases, investigations by medical societies and other organizations have found some expert witnesses to be total charlatans. They may not even have a medical degree (that they do not buy out of the catalog). As a consequence, many of the scientific research experts at the top of their fields will not participate in court proceedings because they are not convinced it is about trying to find the truth. To them, it is a total circus atmosphere and a dramatic passion play which has nothing to do with scientific evidence.

Legal experts who have interviewed juries coming out of these cases note that juries do not even think the case is about weighing the scientific evidence. They think that the case is about which lawyer they like the most, which is the most dramatic, which is the most convincing. They often think it is a moral question between the poor victim and the big corporation - never mind the facts.

Needless to say, after Dr. Angell's editorial and when all of this was published, she received a significant response from the plaintiffs' attorneys involved in the implants class action case. She was served by two subpoenas within a year. The attorneys accused her of being paid by the implant manufacturers. They requested any records or communication between her and the manufacturers. Of course, none of these records existed because there had been no communication between Dr. Angell and any of the implant manufacturers. However, the harassment did not stop there. Dr. Angell was also asked to release confidential records which were used in the peer review process at *The New England Journal of Medicine*. She was taken to court twice, and both times the subpoenas were denied. Later she found that the Mayo Clinic, who had conducted the implant study published in *The New England Journal of Medicine* was also being harassed by subpoenas. Not only did they ask for records regarding the data published in the breast implant study, but they subpoenaed the entire data base at the Mayo Clinic which includes confidential names of patients and doctors, medical data which has been collected by the Mayo Clinic for 150 years in Olmstead County, Minnesota. Because this data base is so invaluable, not only to the Mayo Clinic but to the world at large, the Mayo Clinic

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understandably was reluctant to relinquish the data base to the attorneys. Also, as confidentiality of their research was threatened and doctors and patients pulled out of research studies, research, in general, was basically shut down at the Mayo Clinic, so the plaintiffs' attorneys got basically what they wanted: a moratorium on breast implant research. It was not worth it to the Mayo Clinic to risk all research. It was easier to give up doing breast implant research. Since the Mayo Clinic study was published in 1994, ten other peer-reviewed studies on breast implants have been conducted. None of these studies have found any link between breast implants and disease.

Now, what has happened in the aftermath of all this and what have we learned? Obviously, this has sent quite a strong message to the medical device industry and will, no doubt, have an incredible impact on anything which is silicone based including dialysis tubing, hydrocephalus shunts, Norplant, heart valves, artificial joints, not to mention the other supplies and devices which have been affected by the fallout of this huge class action suit. Dupont has already pulled out of the medical device industry and says it will no longer supply dacron graft materials for vascular grafts (used in heart surgery). The class action settlement against Dow collapsed, and Dow has now filed bankruptcy. The economic impact on this country as a result, one can only guess. The economic impact on plaintiffs' attorneys involved in the case is that they cleared \$1 billion in attorney fees. This has even caused ripples in some parts of the legal community, specifically the Yale School of Law, reportedly the #1 law school in the United States. There, an assistant professor, E. Donald Elliot, said that "the tort lawyers perpetuated a fraud" (earning them a billion dollars), and called the class action tort system "a public health issue."

Fewer and fewer pharmaceutical companies are willing to do research on contraception due to liability issues - contraception like birth control pills which saves the United States billions of health care dollars every year, not to mention thousand of lives. Fewer and fewer pharmaceutical companies are willing to make vaccines. There used to be twenty pharmaceutical companies who made vaccines, and now there are only four. Medical research in other medical arenas is practically strangled. As law professor Elliott states, "Economics drives the system, and until we address this, there will be no change in the tort system."

These same issues prompted Yale law professor John Langbein to state: "The American legal system is the laughing stock in the civilized world. We have a legal system that encourages people not to do business in this country. We have a legal system that gets ever more expensive and that causes us to pay monumental insurance premiums compared to the rest of the civilized world. We have a legal system that is a flop." He goes on to say: "We have lawyers running the system, and that is the problem. Lawyers do not have an obligation and a commitment to the truth. Lawyers have an obligation to win, so we have a combat system rather than a truth system." Professor Elliott echoes this by stating in his law review article of 1989 that "one of the problems with the present legal system is that it extends equal dignity to charlatans and Nobel Prize winners with only a lay jury to distinguish between the two." Dr. Angell's rather harrowing experience with the legal system has prompted her to write a book called *Science on Trial*, illustrating the danger to us as a public when we try to answer scientific questions in the absence of evidence.

This problem is not just a problem in the medical community alone; it is a problem cited among scientists at large. You need only to walk into Borders Books or Barnes & Nobles to see the shelves burgeoning with frustrated scientists and researchers who are dealing with a world and a society that turns to pseudo-science and superstition to answer important questions which may affect our lives, our children's lives, and our planet as a whole.

In Carl Sagan's recent book, which was a New York Times best seller for many weeks, called *The Demon-Haunted World: Science as a Candle in the Darkness*, he states how necessary science is in a healthy democracy. "The values of science and the values of democracy are concordant, in many cases indistinguishable. Science and democracy began in their civilized incarnations in the same time and place, Greece in the seventh and sixth centuries B.C. Science confers power on anyone who takes the trouble to learn it... Science thrives on, and indeed, requires the free exchange of ideas; its values are antithetical to secrecy. Science holds to no special vantage points or privileged positions. Both science and democracy encourage unconventional opinions and vigorous debate. Both demand adequate reason, coherent argument, rigorous standards of evidence and honesty. Science is a way to call the bluff of those who only pretend to knowledge."

As a legislator, I ask that you make a vote for sanity and reason. Anyone, at this point, who argues that the current tort system is in the best interest of the community or the public at large has not looked at the facts. What is wrong with this system, they ask. Merrell-Dow is a big company - they can afford it, they can afford that kind of money. So what if there is no scientific evidence to back it up? Where is the harm?

The harm is women who are so frightened by the claims that they tried to cut out their own implants with razor blades. The harm is \$4.25 billion which could have been spent on something else besides lining the pockets of lawyers. What could we do with \$4.25 billion if that was pumped back into the public health system? Oh, let my imagination wander! But most of all, the harm is in the lie, the lie that has been perpetuated by fear, fear that is unsubstantiated by fact, the lie that might deprive you of a heart valve or your child of a shunt that might save his or her life, or untold fantastic treatments, devices and cures that might lie on the horizon. I cannot support a system that intimidates and harasses our brightest minds in medicine or that dictates what research will or will not be done based on whether or not they agree with the results. That is very dangerous. That is behavior that should not be tolerated by any state legislature. Only if we attack this problem, state by state, will it ever be solved on a national level.

So, I ask for your vote: I ask for your vote for reform. I ask for your vote for sanity. I ask for your vote for reason. I ask you to support science, the candle in the darkness that is flickering before you. Please, please do not let it go out!

Thank you very much for your consideration.

Sincerely,



Cynthia L. Brooke, MD

/plc

JAN 28 '96

**STATE OF MICHIGAN
88TH LEGISLATURE
REGULAR SESSION OF 1995**

Introduced by Senators Gougeon, Shugars, Cisky, Emmons, North, Schwarz, Carl, McManus, Steil,
Geake, Rogers, Stille, Gast, Schuette and Bennett

ENROLLED SENATE BILL No. 344

AN ACT to amend sections 1629, 1641, 2945, 2946, 2947, 2948, 2957, and 6304 of Act No. 236 of the Public Acts of 1961, entitled as amended "An act to revise and consolidate the statutes relating to the organization and jurisdiction of the courts of this state; the powers and duties of such courts, and of the judges and other officers thereof; the forms and attributes of civil claims and actions; the time within which civil actions and proceedings may be brought in said courts; pleading, evidence, practice and procedure in civil and criminal actions and proceedings in said courts; to provide remedies and penalties for the violation of certain provisions of this act; and to repeal all acts and parts of acts inconsistent with, or contravening any of the provisions of this act," sections 1629, 1641, 2945, 2948, and 6304 as amended and section 2957 as added by Act No. 161 of the Public Acts of 1995, being sections 600.1629, 600.1641, 600.2945, 600.2946, 600.2947, 600.2948, 600.2957, and 600.6304 of the Michigan Compiled Laws; to add sections 2946a, 2949a, 2955, 2955a, 2962, and 6312; and to repeal acts and parts of acts.

The People of the State of Michigan enact:

Section 1. Sections 1629, 1641, 2945, 2946, 2947, 2948, 2957, and 6304 of Act No. 236 of the Public Acts of 1961, sections 1629, 1641, 2945, 2948, and 6304 as amended and section 2957 as added by Act No. 161 of the Public Acts of 1995, being sections 600.1629, 600.1641, 600.2945, 600.2946, 600.2947, 600.2948, 600.2957, and 600.6304 of the Michigan Compiled Laws, are amended and sections 2946a, 2949a, 2955, 2955a, 2962, and 6312 are added to read as follows:

Sec. 1629. (1) Subject to subsection (2), in an action based on tort or another legal theory seeking damages for personal injury, property damage, or wrongful death, all of the following apply:

(a) The county in which the original injury occurred and in which either of the following applies is a county in which to file and try the action:

(i) The defendant resides, has a place of business, or conducts business in that county.

(ii) The corporate registered office of a defendant is located in that county.

(b) If a county does not satisfy the criteria under subdivision (a), the county in which the original injury occurred and in which either of the following applies is a county in which to file and try the action:

(i) The plaintiff resides, has a place of business, or conducts business in that county.

(ii) The corporate registered office of a plaintiff is located in that county.

(c) If a county does not satisfy the criteria under subdivision (a) or (b), a county in which both of the following apply is a county in which to file and try the action:

(i) The plaintiff resides, has a place of business, or conducts business in that county, or has its corporate registered office located in that county.

(ii) The defendant resides, has a place of business, or conducts business in that county, or has its corporate registered office located in that county.

(d) If a county does not satisfy the criteria under subdivision (a), (b), or (c), a county that satisfies the criteria under section 1621 or 1627 is a county in which to file and try an action.

(2) Any party may file a motion to change venue based on hardship or inconvenience.

(3) For the purpose of this section only, in a product liability action, a defendant is considered to conduct business in a county in which the defendant's product is sold at retail.

Sec. 1641. (1) Except as provided in subsection (2), if causes of action are joined, whether properly or not, venue is proper in any county in which either cause of action, if sued upon separately, could have been commenced and tried, subject to separation and change as provided by court rule.

(2) If more than 1 cause of action is pleaded in the complaint or added by amendment at any time during the action and 1 of the causes of action is based on tort or another legal theory seeking damages for personal injury, property damage, or wrongful death, venue shall be determined under the rules applicable to actions in tort as provided in section 1629.

Sec. 2945. As used in this section and sections 1629, 2945 to 2949a, and 5805:

(a) "Alteration" means a material change in a product after the product leaves the control of the manufacturer or seller. Alteration includes a change in the product's design, packaging, or labeling; a change to or removal of a safety feature, warning, or instruction; deterioration or damage caused by failure to observe routine care and maintenance or failure to observe an installation, preparation, or storage procedure; or a change resulting from repair, renovation, reconditioning, recycling, or reclamation of the product.

(b) "Drug" means that term as defined in section 201 of the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. §21. However, drug does not include a medical appliance or device.

(c) "Economic loss" means objectively verifiable pecuniary damages arising from medical expenses or medical care, rehabilitation services, custodial care, loss of wages, loss of future earnings, burial costs, loss of use of property, costs of repair or replacement of property, costs of obtaining substitute domestic services, loss of employment, or other objectively verifiable monetary losses.

(d) "Gross negligence" means conduct so reckless as to demonstrate a substantial lack of concern for whether injury results.

(e) "Misuse" means use of a product in a materially different manner than the product's intended use. Misuse includes uses inconsistent with the specifications and standards applicable to the product, uses contrary to a warning or instruction provided by the manufacturer, seller, or another person possessing knowledge or training regarding the use or maintenance of the product, and uses other than those for which the product would be considered suitable by a reasonably prudent person in the same or similar circumstances.

(f) "Noneconomic loss" means any type of pain, suffering, inconvenience, physical impairment, disfigurement, mental anguish, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, humiliation, or other nonpecuniary damages.

(g) "Product" includes any and all component parts to a product.

(h) "Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product.

(i) "Production" means manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling.

(j) "Sophisticated user" means a person or entity that, by virtue of training, experience, a profession, or legal obligations, is or is generally expected to be knowledgeable about a product's properties, including a potential hazard or adverse effect. An employee who does not have actual knowledge of the product's potential hazard or adverse effect that caused the injury is not a sophisticated user.

Sec. 2946. (1) It shall be admissible as evidence in a product liability action that the production of the product was in accordance with the generally recognized and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.

(2) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a production defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that, according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm.

without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

(3) With regard to the production of a product that is the subject of a product liability action, evidence of a philosophy, theory, knowledge, technique, or procedure that is learned, placed in use, or discontinued after the event resulting in the death of the person or injury to the person or property, which if learned, placed in use, or discontinued before the event would have made the event less likely to occur, is admissible only for the purpose of proving the feasibility of precautions, if controverted, or for impeachment.

(4) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a regulation or standard not relevant to the event causing the death or injury is not admissible.

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 342-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Sec. 2946a. (1) In an action for product liability, the total amount of damages for noneconomic loss shall not exceed \$280,000.00, unless the defect in the product caused either the person's death or permanent loss of a vital bodily function, in which case the total amount of damages for noneconomic loss shall not exceed \$500,000.00. On the effective date of the amendatory act that added this section, the state treasurer shall adjust the limitations set forth in this subsection so that the limitations are equal to the limitations provided in section 1483. After that date, the state treasurer shall adjust the limitations set forth in this subsection at the end of each calendar year so that they continue to be equal to the limitations provided in section 1483.

(2) In awarding damages in a product liability action, the trier of fact shall itemize damages into economic and noneconomic losses. Neither the court nor counsel for a party shall inform the jury of the limitations under subsection (1). The court shall adjust an award of noneconomic loss to conform to the limitations under subsection (1).

(3) The limitation on damages under subsection (1) for death or permanent loss of a vital bodily function does not apply to a defendant if the trier of fact determines by a preponderance of the evidence that the death or loss was the result of the defendant's gross negligence, or if the court finds that the matters stated in section 2949a are true.

(4) If damages for economic loss cannot readily be ascertained by the trier of fact, then the trier of fact shall calculate damages for economic loss based on an amount that is equal to the state average median family income as reported in the immediately preceding federal decennial census and adjusted by the state treasurer in the same manner as provided in subsection (1).

Sec. 2947. (1) A manufacturer or seller is not liable in a product liability action for harm caused by an alteration of the product unless the alteration was reasonably foreseeable. Whether there was an alteration of a product and whether an alteration was reasonably foreseeable are legal issues to be resolved by the court.

(2) A manufacturer or seller is not liable in a product liability action for harm caused by misuse of a product unless the misuse was reasonably foreseeable. Whether there was misuse of a product and whether misuse was reasonably foreseeable are legal issues to be resolved by the court.

(3) A manufacturer or seller is not liable in a product liability action if the purchaser or user of the product was aware that use of the product created an unreasonable risk of personal injury and voluntarily exposed himself or herself to that risk and the risk that he or she exposed himself or herself to was the proximate cause of the injury. This subsection does not relieve a manufacturer or seller from a duty to use reasonable care in a product's production.

(4) Except to the extent a state or federal statute or regulation requires a manufacturer to warn, a manufacturer or seller is not liable in a product liability action for failure to provide an adequate warning if the product is provided for use by a sophisticated user.

(5) A manufacturer or seller is not liable in a product liability action if the alleged harm was caused by an inherent characteristic of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability, and that is recognized by a person with the ordinary knowledge common to the community.

(6) In a product liability action, a seller other than a manufacturer is not liable for harm allegedly caused by the product unless either of the following is true:

(a) The seller failed to exercise reasonable care, including breach of any implied warranty, with respect to the product and that failure was a proximate cause of the person's injuries.

(b) The seller made an express warranty as to the product, the product failed to conform to the warranty, and the failure to conform to the warranty was a proximate cause of the person's harm.

Sec. 2948. (1) Evidence is admissible in a product liability action that, before the death of the person or injury to the person or damage to property, pamphlets, booklets, labels, or other written warnings were provided that gave notice to foreseeable users of the material risk of injury, death, or damage connected with the foreseeable use of the product or provided instructions as to the foreseeable uses, applications, or limitations of the product that the defendant knew or should have known.

(2) A defendant is not liable for failure to warn of a material risk that is or should be obvious to a reasonably prudent product user or a material risk that is or should be a matter of common knowledge to persons in the same or similar position as the person upon whose injury or death the claim is based in a product liability action.

(3) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions, a manufacturer or seller is not liable unless the plaintiff proves that the manufacturer knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.

(4) This section does not limit a manufacturer's or seller's duty to use reasonable care in relation to a product after the product has left the manufacturer's or seller's control.

Sec. 2949a. In a product liability action, if the court determines that at the time of manufacture or distribution the defendant had actual knowledge that the product was defective and that there was a substantial likelihood that the defect would cause the injury that is the basis of the action, and the defendant willfully disregarded that knowledge in the manufacture or distribution of the product, then sections 2946(4), 2946a, 2947(1) to (4), and 2948(2) do not apply.

Sec. 2955. (1) In an action for the death of a person or for injury to a person or property, a scientific opinion rendered by an otherwise qualified expert is not admissible unless the court determines that the opinion is reliable and will assist the trier of fact. In making that determination, the court shall examine the opinion and the basis for the opinion, which basis includes the facts, technique, methodology, and reasoning relied on by the expert, and shall consider all of the following factors:

(a) Whether the opinion and its basis have been subjected to scientific testing and replication.

(b) Whether the opinion and its basis have been subjected to peer review publication.

(c) The existence and maintenance of generally accepted standards governing the application and interpretation of a methodology or technique and whether the opinion and its basis are consistent with those standards.

(d) The known or potential error rate of the opinion and its basis.

(e) The degree to which the opinion and its basis are generally accepted within the relevant expert community. As used in this subdivision, "relevant expert community" means individuals who are knowledgeable in the field of study and are gainfully employed applying that knowledge on the free market.

(f) Whether the basis for the opinion is reliable and whether experts in that field would rely on the same basis to reach the type of opinion being proffered.

(g) Whether the opinion or methodology is relied upon by experts outside of the context of litigation.

(2) A novel methodology or form of scientific evidence may be admitted into evidence only if its proponent establishes that it has achieved general scientific acceptance among impartial and disinterested experts in the field.

(3) In an action alleging medical malpractice, the provisions of this section are in addition to, and do not otherwise affect, the criteria for expert testimony provided in section 2169.

Sec. 2955a. (1) It is an absolute defense in an action for the death of an individual or for injury to a person or property that the individual upon whose death or injury the action is based had an impaired ability to function due to the influence of intoxicating liquor or a controlled substance, and as a result of that impaired ability, the individual was 50% or more the cause of the accident or event that resulted in the death or injury. If the individual described in this subsection was less than 50% the cause of the accident or event, an award of damages shall be reduced by that percentage.

(2) As used in this section:

(a) "Controlled substance" means that term as defined in section 7104 of the public health code, Act No. 368 of the Public Acts of 1978, being section 333.7104 of the Michigan Compiled Laws.

(b) "Impaired ability to function due to the influence of intoxicating liquor or a controlled substance" means that, as a result of an individual drinking, ingesting, smoking, or otherwise consuming intoxicating liquor or a controlled substance, the individual's senses are impaired to the point that the ability to react is diminished from what it would be had the individual not consumed liquor or a controlled substance. An individual is presumed under this section to have an impaired ability to function due to the influence of intoxicating liquor or a controlled substance if, under a standard prescribed by section 625a of the Michigan vehicle code, Act No. 300 of the Public Acts of 1949, being section 257.625a of the Michigan Compiled Laws, a presumption would arise that the individual's ability to operate a vehicle was impaired.

Sec. 2957. (1) In an action based on tort or another legal theory seeking damages for personal injury, property damage, or wrongful death, the liability of each person shall be allocated under this section by the trier of fact and, subject to section 6304, in direct proportion to the person's percentage of fault. In assessing percentages of fault under this subsection, the trier of fact shall consider the fault of each person, regardless of whether the person is, or could have been, named as a party to the action.

(2) Upon motion of a party within 91 days after identification of a nonparty, the court shall grant leave to the moving party to file and serve an amended pleading alleging 1 or more causes of action against that nonparty. A cause of action added under this subsection is not barred by a period of limitation unless the cause of action would have been barred by a period of limitation at the time of the filing of the original action.

(3) Sections 2956 to 2960 do not eliminate or diminish a defense or immunity that currently exists, except as expressly provided in those sections. Assessments of percentages of fault for nonparties are used only to accurately determine the fault of named parties. If fault is assessed against a nonparty, a finding of fault does not subject the nonparty to liability in that action and shall not be introduced as evidence of liability in another action.

Sec. 2962. This section applies to an action for professional malpractice against a certified public accountant. A certified public accountant is liable for civil damages in connection with public accounting services performed by the certified public accountant only in 1 of the following situations:

(a) A negligent act, omission, decision, or other conduct of the certified public accountant if the claimant is the certified public accountant's client.

(b) An act, omission, decision, or conduct of the certified public accountant that constitutes fraud or an intentional misrepresentation.

(c) A negligent act, omission, decision, or other conduct of the certified public accountant if the certified public accountant was informed in writing by the client at the time of engagement that a primary intent of the client was for the professional public accounting services to benefit or influence the person bringing the action for civil damages. For the purposes of this subdivision, the certified public accountant shall identify in writing to the client each person, generic group, or class description that the certified public accountant intends to have rely on the services. The certified public accountant may be held liable only to each identified person, generic group, or class description. The certified public accountant's written identification shall include each person, generic group, or class description identified by the client as being benefited or influenced.

Sec. 6304. (1) In an action based on tort or another legal theory seeking damages for personal injury, property damage, or wrongful death involving fault of more than 1 person, including third-party defendants and nonparties, the

court, unless otherwise agreed by all parties to the action, shall instruct the jury to answer special interrogatories or, if there is no jury, shall make findings indicating both of the following:

- (a) The total amount of each plaintiff's damages.
- (b) The percentage of the total fault of all persons that contributed to the death or injury, including each plaintiff and each person released from liability under section 2925d, regardless of whether the person was or could have been named as a party to the action.

(2) In determining the percentages of fault under subsection (1)(b), the trier of fact shall consider both the nature of the conduct of each person at fault and the extent of the causal relation between the conduct and the damages claimed.

(3) The court shall determine the award of damages to each plaintiff in accordance with the findings under subsection (1), subject to any reduction under subsection (5) or section 2955a or 6303, and shall enter judgment against each party, including a third-party defendant, except that judgment shall not be entered against a person who has been released from liability as provided in section 2925d.

(4) Liability in an action to which this section applies is several only and not joint. Except as otherwise provided in subsection (6), a person shall not be required to pay damages in an amount greater than his or her percentage of fault as found under subsection (1). This subsection and section 2956 do not apply to a defendant that is jointly and severally liable under section 6312.

(5) In an action alleging medical malpractice, the court shall reduce an award of damages in excess of 1 of the limitations set forth in section 1483 to the amount of the appropriate limitation set forth in section 1483. The jury shall not be advised by the court or by counsel for either party of the limitations set forth in section 1483 or any other provision of section 1483.

(6) If an action includes a medical malpractice claim against a person or entity described in section 5838a(1), 1 of the following applies:

(a) If the plaintiff is determined to be without fault under subsections (1) and (2), the liability of each defendant is joint and several, whether or not the defendant is a person or entity described in section 5838a(1).

(b) If the plaintiff is determined to have fault under subsections (1) and (2), upon motion made not later than 6 months after a final judgment is entered, the court shall determine whether all or part of a party's share of the obligation is uncollectible from that party, and shall reallocate any uncollectible amount among the other parties, whether or not another party is a person or entity described in section 5838a(1), according to their respective percentages of fault as determined under subsection (1). A party is not required to pay a percentage of any uncollectible amount that exceeds that party's percentage of fault as determined under subsection (1). The party whose liability is reallocated continues to be subject to contribution and to any continuing liability to the plaintiff on the judgment.

(7) Notwithstanding subsection (6), a governmental agency, other than a governmental hospital or medical care facility, is not required to pay a percentage of any uncollectible amount that exceeds the governmental agency's percentage of fault as determined under subsection (1).

(8) As used in this section, "fault" includes an act, an omission, conduct, including intentional conduct, a breach of warranty, or a breach of a legal duty, or any conduct that could give rise to the imposition of strict liability, that is a proximate cause of damage sustained by a party.

Sec. 6312. A defendant that is found liable for an act or omission that causes personal injury, property damage, or wrongful death is jointly and severally liable if the defendant's act or omission is any of the following:

- (a) A crime, an element of which is gross negligence, for which the defendant is convicted.
- (b) A crime involving the use of alcohol or a controlled substance for which the defendant is convicted and that is a violation of 1 or more of the following:
 - (i) Section 14 of the explosives act of 1970, Act No. 202 of the Public Acts of 1970, being section 29.54 of the Michigan Compiled Laws.
 - (ii) Section 111 of the Michigan code of military justice of 1980, Act No. 523 of the Public Acts of 1980, being section 32.1111 of the Michigan Compiled Laws.
 - (iii) Section 625 of the Michigan vehicle code, Act No. 300 of the Public Acts of 1949, being section 257.625 of the Michigan Compiled Laws.
 - (iv) Section 185 of the aeronautics code of the state of Michigan, Act No. 327 of the Public Acts of 1945, being section 259.185 of the Michigan Compiled Laws.
 - (v) Section 80176 of part 801 (marine safety), 81134 of part 811 (off-road recreation vehicles), or 82127 of part 821 (snowmobiles) of the natural resources and environmental protection act, Act No. 451 of the Public Acts of 1994, being sections 324.80176, 324.81134, and 324.82127 of the Michigan Compiled Laws.
 - (vi) Section 353 of the railroad code of 1993, Act No. 354 of the Public Acts of 1993, being section 462.353 of the Michigan Compiled Laws.

(vii) Section 237 of the Michigan penal code, Act No. 328 of the Public Acts of 1931, being section 750.237 of the Michigan Compiled Laws.

Section 2. Section 2949 of Act No. 236 of the Public Acts of 1961, being section 600.2949 of the Michigan Compiled Laws, is repealed.

Section 3. Sections 1629, 1641, 2945, 2946, 2947, 2948, 2957, and 6304 of Act No. 236 of the Public Acts of 1961, being sections 600.1629, 600.1641, 600.2945, 600.2946, 600.2947, 600.2948, 600.2957, and 600.6304 of the Michigan Compiled Laws, as amended by this amendatory act, and sections 2946a, 2949a, 2955, 2955a, 2962, and 6312 of Act No. 236 of the Public Acts of 1961, being sections 600.2946a, 600.2949a, 600.2955, 600.2955a, 600.2962, and 600.6312 of the Michigan Compiled Laws, as added by this amendatory act, apply to actions filed on or after the effective date of this amendatory act.

Carol Morey Viventi

Secretary of the Senate.

Allen R. Beyer

Clerk of the House of Representatives.

Approved _____

Governor.



FAX TRANSMISSION
from fax (202) 682-1022

TO: Jim

FIRM: DOT Ref Porter

American Tort Reform Association

1212 New York Avenue, N.W.
Suite 515
Washington, D.C. 20005
(202) 682-1163

FAX NO#: 907 465-3834

FROM: L. LeCham

SUBJECT: SEC 295 Address EXPERT WITNESS/
Scientific testimony

COMMENTS: * SB 344 Passed ED 1995

RESPONSE REQUESTED yes ☐ no ☐

Total pages including cover 8 sent by Date sent

4-1-97
few
amendments

POSSIBLE AMENDMENT TO ALASKA EVIDENCE RULE 702 IS IN
CAPITAL LETTERS:

Rule 702. Testimony by Experts

(a) 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. IT SHALL BE AN ~~ABSOLUTE~~ PREREQUISITE TO ADMISSIBILITY OF SCIENTIFIC ~~AND~~ TECHNICAL EVIDENCE THAT THE SCIENTIFIC TECHNIQUE, DISCOVERY OR PRINCIPLE ON WHICH SUCH EVIDENCE IS BASED IS SUFFICIENTLY ESTABLISHED TO HAVE GENERAL ACCEPTANCE IN THE FIELD TO WHICH IT BELONGS, ~~INCLUDING VALIDATION BY PUBLICATION AND PEER REVIEW.~~

DRAFT #2
4-1-97

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DRAFT #2
4.1.97

Post-It® Fax Note 7671		Date 3.31	# of pages 1
To DA. BROOKE	From TIM SUBRANT		
Co./Dept.	Co. Rep. Porter.		
Phone #	Phone 465-3727		
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POSSIBLE AMENDMENT TO ALASKA EVIDENCE RULE 702 IS IN CAPITAL LETTERS:

Rule 702. Testimony by Experts

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DR. BROOKE:
DOES THIS LANGUAGE (CAPS)
MAKE SENSE TO YOU?
Tim
S,

Brooke

Post-it® Fax Note 7671		Date 4.1.97	# of pages 1
To LARRY LACROIX	From JIM SOURANT		
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Post-it® Fax Note 7671		Date 4.1.97	# of pages 1
To ROGER HOLMES	From JIM SOURANT		
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Fax # 206-340-0289	Fax #		

Post-it® Fax Note 7671		Date 4.1.97	# of pages 1
To MIKE LESSMEIER	From JIM S. O. Rep.		
Co./Dept.	Co. BRIAN PORTER		
Phone #	Phone # 465-4930		
Fax # 463-3020	Fax #		

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res followed the property into the hands of Kelly Electric. Therefore, we REVERSE the superior court's grant of summary judgment in favor of Kelly Electric. REMAND this matter to the superior court with directions to reinstate Kelly Electric as the defendant and for such other proceedings as are consistent with this opinion.



Stephen J. HARMON, Appellant,

v.

STATE of Alaska, Appellee.

No. A-5139.

Court of Appeals of Alaska.

Dec. 22, 1995.

Defendant was convicted in the Superior Court, Fourth Judicial District, Fairbanks, by Judge J. Steinkruger, J., of sexual assault in the second degree and murder in first degree. Defendant appealed. The Court of Appeals, by Judge J., held that: (1) speedy trial time began to run when defendant was arraigned on indictment; (2) evidence of defendant's admission of prior crimes was sufficiently reliable to warrant admission of evidence; (3) deoxyribonucleic acid (DNA) testing was generally accepted within scientific community and human population geneticists to warrant admission of results of tests; and (4) sufficient evidence supported aggravating factor of manifesting deliberate cruelty during commission of offense.

Affirmed.

Criminal Law §577.8(2)

Speedy trial time in prosecution for sexual assault and murder began to run when defendant was arraigned on indictment rather than when he was taken into custody by

federal authorities for federal firearms violation. Rules of Evid., Rules 403, 404(b).

2. Criminal Law §1035(1)

Defendant waived issue of whether indictment against him should have been dismissed on basis that state improperly introduced deoxyribonucleic acid (DNA) evidence during grand jury proceedings and implied that DNA evidence was routinely admissible in state, since defendant never raised claim in trial court. Rules Crim.Proc., Rule 12(e).

3. Criminal Law §372(4, 7)

Similarity between defendant's prior sexual assaults and murder of victim in instant case were sufficiently similar to permit introduction of prior crimes evidence; like victims of defendant's prior sexual assaults, victim was white single female who had previously met defendant in social setting and subsequently rejected his offers of romantic relationship, defendant had physically assaulted two prior victims, and evidence showed that victim had been beaten, defendant used knife in prior assaults and evidence showed that victim's assailant had cut her with knife, defendant had used electrical cord to tie hands of prior victims, and victim's assailant wrapped electrical cord around her neck. Rules of Evid., Rules 403, 404; Rules Crim.Proc., Rule 45.

4. Criminal Law §372(4, 7)

Evidence of prior crimes in prosecution of defendant for sexual assault and murder were not rendered inadmissible as remote on basis that they had occurred 12 years before acts which gave rise to instant prosecution, since defendant had been incarcerated for eight of those 12 years, evidence was strong that defendant had committed prior assaults, and two prior assaults were similar to circumstances of victim's murder. Rules of Evid., Rules 403, 404(b); Rules Crim.Proc., Rule 45.

5. Criminal Law §388.2

Deoxyribonucleic acid (DNA) testing by restriction fragment length polymorphism typing (RFLP) and polymerase chain reaction typing (PCR) are generally accepted in scientific community of human population

geneticists, and so such test results are admissible in criminal prosecutions.

6. Criminal Law §388.2

Statistical analysis of deoxyribonucleic acid (DNA) testing allowed for population substructures and conservatively estimated probability of match, and so was admissible in prosecution of defendant for sexual assault and murder.

7. Criminal Law §700(9)

Fact that state consumed evidence of blood stains on watch of defendant and electrical cord found at crime scene, anal swabs from victim, and hairs from victim's underpants in performing deoxyribonucleic acid (DNA) tests on evidence did not render test results inadmissible in prosecution for sexual assault and murder; state experts made substantial efforts to preserve evidence of their testing so that defense experts would be able to review state's results, there was still substantial evidence left over after state tests so that defense could perform its own tests, and testing was done during investigative stage.

8. Assault and Battery §100

Homicide §354(1)

Trial court's finding of aggravating factor that defendant's conduct during commission of offense manifested deliberate cruelty to another person during sentencing of defendant for conviction of sexual assault and murder was supported by evidence that defendant had premeditated offense and had used his friendship with victim to gain entry into her home, that defendant tortured victim by poking and cutting her with knife and strangling her with piece of electrical cord, and that defendant had not only sexually assaulted and murdered victim, but that he had tortured her for his own sexual gratification. AS 12.55.155(c)(2).

9. Assault and Battery §100

Homicide §354(1)

Restriction of parole eligibility of defendant who was convicted of sexual assault and murder, for 99 years, was justified by defendant's prior criminal history of sexual assault, seriousness of his present offense, and his poor rehabilitation potential.

es for federal firearms viola-
vid., Rules 403, 404(b).

w ⇨1035(1)

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t him should have been dis-
that state improperly intro-
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and murder of victim in in-
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prior crimes evidence; like
ndant's prior sexual assaults,
e single female who had pre-
defendant in social setting and
ejected his offers of romantic
defendant had physically as-
prior victims, and evidence
ctim had been beaten, defen-
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that victim's assailant had cut
defendant had used electrical
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t wrapped electrical cord
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n.Proc., Rule 45.

w ⇨372(4, 7)

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dant who was convicted of sexual assault and
murder, for 99 years, was justified by defen-
dant's prior criminal history of sexual as-
sault, seriousness of his present offense, and
his poor rehabilitation potential.

Robert S. Noreen, Fairbanks, for Appel-
lant.

Nancy R. Simel, Assistant Attorney Gener-
al, Office of Special Prosecutions and Ap-
peals, Anchorage, and Bruce M. Botelho, At-
torney General, Juneau, for Appellee.

Before BRYNER, C.J., and COATS and
MANNHEIMER, JJ.

OPINION

COATS, Judge.

I. FACTUAL AND PROCEDURAL BACKGROUND

Either late in the evening of May 15 or
early May 16, 1992, B.K. was sexually as-
saulted and murdered. The state charged
Stephen J. Harmon with sexual assault in the
first degree and murder in the first degree
after the results of DNA testing connected
him with the crime. Following a trial, a jury
convicted Harmon of the sexual assault and
murder. Superior Court Judge Niesje J.
Steinkruger sentenced Harmon to maximum
consecutive sentences of thirty years for the
sexual assault and ninety-nine years for the
murder. Judge Steinkruger also ordered
that Harmon would not be eligible for parole
for ninety-nine years. Harmon appeals his
conviction and sentence. We affirm.

II. ANALYSIS

A. SPEEDY TRIAL

[1] Harmon first contends that Judge
Steinkruger erred in refusing to dismiss the
charges against him under Alaska Criminal
Rule 45, the speedy trial rule. In 1992,
Criminal Rule 45 provided that the state was
required to try a defendant within 120 days,
less certain excluded periods, from either the
date the defendant was arrested or initially
arraigned, or the date the charge (complaint,
indictment, or information) was served on the
defendant, whichever event occurred first.
Harmon argues that the speedy trial period
began on June 12, 1992, when he was taken
into custody by federal authorities for a fed-
eral firearms violation. The state argues
that the speedy trial rule did not start until

Harmon's prior sexual assaults, B.K. was a white single female who had previously met Harmon in a social setting and subsequently rejected his offers of a romantic relationship. Harmon's prior victims had let him into their homes where he assaulted them in their rooms shortly after midnight. Similarly, evidence showed that B.K. let her assailant into her home where she was murdered in her living room about midnight. Harmon had been drinking on the nights of his prior assaults, and, on the night B.K. was murdered, evidence showed that Harmon had been drinking to the point that his speech was slurred.

In addition, Judge Steinkruger found that there were similarities in the nature and manner of the attacks. For instance, Harmon's two prior convictions were for sexual assault. Evidence established that B.K. had been sexually assaulted by her assailant. Harmon had also physically assaulted his two prior victims, and evidence showed that B.K. had been beaten. Harmon had used a knife in his prior assaults; evidence showed that B.K.'s assailant had cut her with a knife. Furthermore, Harmon had used an electrical cord to tie the hands of his victims in the prior sexual assaults. B.K.'s assailant cut an electrical cord from her sewing machine and apparently wrapped the cord around her neck.

We believe that the similarities between Harmon's prior sexual assaults and the murder of B.K. are, if anything, more distinctive than the evidence which the supreme court concluded was sufficiently similar to permit introduction of the prior crimes evidence in *Coleman*. Accordingly, we conclude that Judge Steinkruger did not err in admitting this evidence.

[4] One further point which Harmon raises on this issue deserves comment. Harmon points out that over twelve years passed between the events that led to his previous convictions and the murder of B.K. He contends that these prior convictions were therefore too remote to be sufficiently probative for admission against him. In analyzing this contention, Judge Steinkruger pointed out that Harmon had been incarcerated for eight years, and therefore, for most of the period

of time since his prior convictions, had not had an opportunity to commit a similar offense. She concluded that under these circumstances, given the strength of the evidence that Harmon had committed the prior assaults (which were proven by convictions), and the similarity of the two prior assaults and the circumstances of B.K.'s murder, the evidence was not too remote in time to be admissible. We conclude that Judge Steinkruger's analysis is sound. See *United States v. Hadley*, 918 F.2d 848 (9th Cir.1990); *Coleman*, 621 P.2d at 875-76 n. 8; *State v. Breazeale*, 238 Kan. 714, 714 P.2d 1356, 1363 (1986).

D. DNA TESTING

[5] Harmon next contends that the trial court erred in admitting results of deoxyribonucleic acid (DNA) testing as evidence against him at trial. At issue are two kinds of DNA testing: restriction fragment length polymorphism typing (RFLP) and polymerase chain reaction typing (PCR). The state introduced the results of RFLP testing on anal swabs taken from B.K. and on a semen stain from her underpants. The state also introduced the results of PCR testing on two hairs that were found on and near the victim, the semen sample from her underwear, bloodstains on the electrical cord found at the scene, and bloodstains on Harmon's watch. In all of the DNA testing, the scientists compared the DNA recovered from the crime scene with DNA from known specimens from the victim and from Harmon. Blood samples from two other suspects were analyzed and eliminated as sources of the DNA samples found at the scene. The results of both the RFLP and the PCR testing were highly incriminating of Harmon.

Prior to trial, Harmon filed a motion to suppress the test results. He contended that DNA testing had not achieved sufficient acceptance in the relevant scientific community to be admissible. Judge Steinkruger held an extensive hearing before trial to determine the admissibility of the DNA evidence. At the hearing, the prosecution and defense presented several witnesses who testified about the general scientific acceptance of the DNA testing and the procedures which were fol-

lowed in analyzing the case.³ In addition, the several scientific articles. Following the hearing findings, Judge Steinkruger both RFLP and PCR results in the scientific community of the DNA test results of the DNA test in this case.⁴

1. Frye Test

As Judge Steinkruger's admission of novel scientific evidence in this state by *Frye*, the court commen-

Just when a scientific theory crosses the line between mental and demonstrable to define. Somewhere the evidential force can be recognized, and a long way in admitting deduced from a well principle or discovered which the deduction is sufficiently established to acceptance in the particular it belongs.

3. Testifying for the state, Dr. J. Beroldingen, a molecular forensic supervisor at the State Police Forensic Laboratory, the forensic supervisor of Safety Crime Laboratory, a professor of genetics at the University of Houston.

Testifying for the defense, Dr. J. Thompson, a forensic supervisor at the Seattle Police Department, recently retired as Chief of the Criminalistics Laboratory, County, California; and Dr. J. Chakraborty, a forensic serologist from California.

4. Judge Steinkruger's findings in Appendices A and B.

5. *Frye v. United States*, 339 U.S. 118 (1950). The Alaska Supreme Court in *Pulaski v. State*, 650 P.2d 1070 (1970).

The state questions whether the evidence is reliable in Alaska. The state

Compliance with these procedures must be shown."

In Harmon's case, the state presented extensive testimony concerning the procedures that were followed in conducting the DNA tests. The state also presented extensive testimony that these procedures were valid and had general scientific acceptance. Although Judge Steinkruger rejected the analysis in *People v. Castro*, she concluded in her findings that the laboratories that tested the DNA evidence in Harmon's case followed standard, generally accepted procedures. This finding is supported by the record and makes it unnecessary for us to decide whether *Castro* applies to this case.

The following background information about DNA is from *State v. Cauthron*, 120 Wash.2d 879, 846 P.2d 502, 508 (1993) (footnote omitted):

DNA (deoxyribonucleic acid) is the chemical material contained within an organism's cells which determine that organism's physical composition. Human cells each contain 46 chromosomes, which are arranged in 23 pairs. One chromosome in each pair is inherited from each parent. Approximately 100,000 genes are located on the chromosomes. Genes, which consist of DNA, determine eye, hair, and skin color, the organization of body parts, and virtually everything else about our physical state. Each individual, with the exception of identical twins, has a unique DNA structure which is contained in every nucleated cell. That structure remains constant throughout a human lifetime. It can be found in blood, semen, hair, bone marrow, and other tissues.

DNA typing is a process by which genetic variation between individuals is recognized and catalogued. In criminal investigations, DNA is extracted from human fluid and tissue samples recovered from a crime scene. In RFLP typing, the extracted DNA is enzymatically cut into fragments, which are separated according to their size. Once they have been separated, the fragments are radioactively marked and an x-ray photograph of the DNA is taken. The DNA of suspects is similarly processed and photographed. The image derived from each suspect's DNA

is then compared to the photograph based on the genetic evidence obtained from the crime scene to determine whether they match. RFLP typing is used for larger (dime-size) blood and semen stains. For smaller, older, and weathered evidence, PCR may be used.

In PCR typing, a specific region of the genetic material recovered from the crime scene is copied using enzymes. The copying continues over several repetitions so that the number of specific DNA segments increases exponentially. The amplified DNA, copied millions of times, is then tested against known genetic sequences to determine its character. Once the character of the DNA recovered from the crime scene is ascertained, it can be compared to the genetic makeup of the suspects. PCR testing is less precise than RFLP, and the PCR DNA is more easily contaminated. National Research Council, *DNA Technology in Forensic Science* 36-44 (1992); U.S. Congress, Office of Technology Assessment, *Genetic Witness: Forensic Uses of DNA Tests* 43-50 (1990).

There seems to be little question concerning the scientific acceptance of the theory underlying both RFLP and PCR DNA typing. See, e.g., *Commonwealth v. Curnin*, 409 Mass. 218, 565 N.E.2d 440, 441 (1991); *State v. Schwartz*, 447 N.W.2d 422, 426 (Minn. 1989); *State v. Woodall*, 385 S.E.2d 253, 260 (W.Va.1989). See also William C. Thompson & Simon Ford, *DNA Typing: Acceptance and Weight of the New Genetic Identification Tests*, 75 Va.L.Rev. 45, 60 (1989).

[6] Judge Steinkruger found that the techniques and procedures relied upon to test the evidence in this case were generally accepted in the scientific community as capable of producing reliable results. She found that the tests performed in this case are "routinely performed and are generally accepted in the relevant scientific community of molecular biologists, DNA forensic scientists, biochemists and population geneticists." She found that the witnesses who testified "explained the controls that were used to insure reliable results generally and in these tests specifically." She also found that "recent cross validation studies between RFLP and PCR provide the most recent evidence of

[DNA testing's] scientific forensic purposes." Judge [redacted] findings are fully supported by

8. Statistical Analysis

Theoretically, each person is unique; that is, with the exception of identical twins, no two persons have the same complement of genes. At the same time, however, it is rare for a gene to be unique to a single person. For instance, the genes that code for our bodies to form two arms are found in virtually everyone. Other genes, such as those that code for skin, hair, and eye color, are found in substantial numbers of people. Some genes are so rare that they are found in small percentages of the general population. Tests for these rare genes are used in minority cases. See *Smith v. State*, 1090 (Alaska 1993).

That genes are shared by many people is of crucial significance when they are employed to identify the perpetrator of a crime. Even though DNA testing can rarely identify a person's genes, the fact that a person carries a particular gene is little unless scientists can show a likelihood that other people carry the same gene. The fact that a defendant carries the same gene as was found in the victim is taken at the scene of the crime is particularly probative if a high percentage of the population also carry that gene. Conversely, if the gene is quite rare, a DNA match becomes more probative.

Harmon's main attack on the state's use of DNA evidence concerns the state's "population substructures." The state's substructure is a cohesive group of people who generally do not mate with people outside of their group (because

6. Genes are sections of the DNA molecule that determine the production of proteins. In a broader sense, determine a person's physical character. Alleles are the variations of a particular gene. The frequency with which a gene is found in a given population that is at issue in a case refers to genes for the sake of

to the photograph based on
 nce obtained from the crime
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g, a specific region of the
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 PLP, and the PCR DNA is
 ntaminated. National Re-
 DNA Technology in Forensic
 1992); U.S. Congress, Office
 ssessment, *Genetic Witness:
 of DNA Tests* 43-50 (1990).

to be little question concern-
 ic acceptance of the theory
 RFLP and PCR DNA typ-
Commonwealth v. Curnin, 409
 N.E.2d 440, 441 (1991); *State*
 7 N.W.2d 422, 426 (Minn.
Woodall, 385 S.E.2d 253, 260
 ee also William C. Thompson
*DNA Typing: Acceptance
 the New Genetic Identifica-
 L.Rev. 45, 60 (1989).*

Steinkruger found that the
 procedures relied upon to
 e in this case were generally
 scientific community as capa-
 g reliable results. She found
 performed in this case are
 rmed and are generally ac-
 relevant scientific community of
 ists, DNA forensic scientists,
 population geneticists." She
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 She also found that "recent
 studies between RFLP and
 the most recent evidence of

[DNA testing's] scientific reliability for fo-
 rensic purposes." Judge Steinkruger's find-
 ings are fully supported by the record..

3. Statistical Analysis

Theoretically, each person's DNA is
 unique; that is, with the exception of "identi-
 cal twins," no two persons share exactly the
 same complement of genes.⁶ At the same
 time, however, it is rare for a specific gene to
 be unique to a single individual. Some
 genes—for instance, the genes that direct
 our bodies to form two arms and two legs—
 are found in virtually every human being.
 Other genes, such as those that determine
 skin, hair, and eye color, are shared by sub-
 stantial numbers of people. Still other genes
 are so rare that they are shared by only
 small percentages of the general population.
 Tests for these rare genes are used in pater-
 nity cases. See *Smith v. Smith*, 845 P.2d
 1090 (Alaska 1993).

That genes are shared by groups of people
 is of crucial significance when DNA testing is
 employed to identify the perpetrator of a
 crime. Even though DNA testing can accu-
 rately identify a person's genes, the fact that
 a person carries a particular gene means
 little unless scientists can also tell us the
 likelihood that other people share that same
 gene. The fact that a defendant carries the
 same gene as was found in a tissue sample
 taken at the scene of the crime is not particu-
 larly probative if a high percentage of the
 population also carry that same gene; con-
 versely, if the gene is quite rare, then the
 DNA match becomes correspondingly more
 probative.

Harmon's main attack on the admissibility
 of DNA evidence concerns the problem of
 "population substructures." A population
 substructure is a cohesive group of people
 who generally do not mate with people out-
 side of their group (because of physical iso-

lation, or because of cultural, racial, or reli-
 gious factors, or a combination of these).

As explained above, the usefulness of DNA
 testing in criminal litigation depends on be-
 ing able to identify what percentage of the
 population carries the particular gene whose
 presence was tested for. Certain critics of
 DNA testing have suggested that the exis-
 tence of population substructures greatly
 complicates this problem, to the point where
 DNA testing has only marginal usefulness.

These critics argue that, even though sci-
 entists may be able to ascertain the frequen-
 cies of particular genes in the general popu-
 lation, this knowledge must be tempered by
 the fact that members of the general popula-
 tion do not mate and reproduce at random.
 Rather, the general population is comprised
 of numerous population substructures, dis-
 tinct groups of people who tend to mate and
 reproduce within their groups. If the people
 in a population substructure have distinctive
 genes, then, because members of the group
 generally do not mate with outsiders, the
 group's distinctive genes would tend to stay
 within the group and not be freely shared
 with the general population. This fact would
 make it harder to calculate the probability
 that a particular individual carried a specific
 gene; probability analyses that ignored the
 presence of population substructures would
 tend to overstate the significance of a DNA
 match. See William C. Thompson, *Evaluat-
 ing the Admissibility of New Genetic Identifi-
 cation Tests: Lessons from the "DNA
 War"*, 84 J.Crim.L. & Criminology 22, 61-65
 (1993). Harmon raises the statistical prob-
 lem of population substructures to attack the
 admissibility of DNA evidence in general.

In the recently enacted AS 12.45.035 (see
 ch. 7 § 2 SLA 1995), the Alaska Legislature
 apparently declared that DNA evidence is
 admissible despite this potential problem.⁷

6. Genes are sections of the DNA molecule gov-
 erning the production of proteins which, in a
 broader sense, determine a person's hereditary
 character. Alleles are the various forms or vari-
 eties of a particular gene. Technically speaking,
 it is the frequency with which alleles occur in a
 given population that is at issue in this case. We
 refer to genes for the sake of simplicity, however.

7. Under AS 12.45.035(a), "evidence of a DNA
 profile is admissible to prove or disprove any
 relevant fact, if the court finds that the technique
 underlying the evidence is scientifically valid.
 The admission of the DNA profile does not re-
 quire a finding of general acceptance in the
 relevant scientific community of DNA profile evi-
 dence."

Harmon's case was tried before the effective date of AS 12.45.035, however; the *Frye* test therefore governed Judge Steinkruger's decision regarding this aspect of the admissibility of the DNA evidence at Harmon's trial.⁸ Judge Steinkruger found that the statistical analysis of the DNA test results satisfied the *Frye* test and was therefore admissible. Having reviewed the record, we agree.

Judge Steinkruger recognized that a statistical analysis which understated the probability of a match between Harmon's DNA and the DNA found at the crime scene (thereby overstating the significance of the match) could be unduly prejudicial. The trial court heard extensive testimony concerning statistical analysis of the matching results. Basically, the testimony showed that the methods that were used to determine the probability of a match incorporated conservative assumptions that, if anything, were designed to overstate the probability of a match. Dr. Jenifer Lindsey, a forensic serologist at the FBI, testified that she calculated and reported the results using a conservative method recommended by the National Research Council. She felt that the method employed accounted for population substructures. Dr. Randjit Chakraborty, a prominent expert in human population genetics, reviewed Dr. Lindsey's findings and approved of the method employed by the FBI. He found the statistical results reported by Dr. Lindsey conservative, accurate, and reliable.

Judge Steinkruger concluded, after hearing the evidence, that the statistical analysis was sufficiently conservative to be admissible. We agree that the extensive testimony presented in this case established that the statistical analysis allowed for the possibility of population substructures and conservatively estimated the probability of a match.

In subsection (b)(2) of the statute, "DNA profile" evidence is defined as

(A) ... an analysis of blood, semen, tissue, or other cells bearing deoxyribonucleic acid resulting in the identification of the individual's patterned chemical structure of genetic information;

(B) [and] includes statistical population frequency comparisons of the patterned chemical structures described in (A) of this paragraph.

Under *Frye* and *Contreras*, we must first determine the relevant scientific community and then decide whether statistical analysis used in this case is generally accepted within that community. We find the relevant scientific community to be human population geneticists and agree with the trial court that the population statistical analyses of the PCR typing and the RFLP matching are generally accepted within the scientific community. We conclude that there was no error in admitting the evidence of DNA typing and the statistical interpretation of this evidence.

4. Consumption of Evidence

[7] Harmon also contended in his motion to suppress that, in the process of testing the DNA taken from the crime scene, the state consumed the evidence of the blood stains on his watch and on the electrical cord, anal swabs from the victim, and hairs from the victim's underpants. Harmon argues that the state violated his right to due process of law by failing to give him the opportunity to have a defense expert observe the state's testing process and by destroying the evidence so that he was unable to conduct independent testing.

In ruling against Harmon's motion, Judge Steinkruger pointed out that the state tested the evidence during the investigative stage of the case before the grand jury indicted Harmon. At that time, the state was comparing the DNA evidence found at the crime scene not only with samples obtained from Harmon but also with DNA obtained from two other suspects. Judge Steinkruger found that the state experts had tested the DNA evidence using sound laboratory procedures, that they had used only as much of the evidence as was necessary for testing, and that they had preserved as much of the evidence as possible for retesting. She observed that even the leading defense expert, Robert Thompson,

8. The passage of the new law presents a potential conundrum: that the DNA evidence could have been inadmissible at the time it was offered but would be admissible at any new trial. We find, however, that the evidence was properly admitted under the *Frye* test, so no problem is presented by the change in the law.

had testified that the state consumed no more evidence than was necessary. Judge Steinkruger found that the state had taken photographs of the watch, and the electrical cord and microscopic photographs, and that Harmon's experts could not find any evidence in the condition of the evidence found it at the crime scene. The state experts testified that the state experts documented their actions and their laboratory notes and that the defense experts so that they followed the state's testing procedures.

Judge Steinkruger found that the state had made available to the defense the amplified DNA from the blood stains on the severed electrical cord and on the watch as well as the hair from the victim's underpants. The defense experts made no attempt to independently test the DNA extracts. As for the anal swabs, Judge Steinkruger found that the state had made the autorads from the RFLP patterns available for review of the RFLP patterns. The state used during RFLP testing the DNA found on the watch as well as Harmon's DNA. A defense expert Thompson testified that it would have been possible to subject the anal swabs to PCR testing. Judge Steinkruger, regarding the possibility of conducting different tests, Judge Steinkruger found that the defense had not requested semen testing by any other method than Harmon's experts desired. Judge Steinkruger found that Harmon had the ability to examine and challenge the state's testing procedures. Judge Steinkruger found that the state had not violated Harmon's rights under Alaska Rule of Criminal Procedure 16 or under due process.

In ruling on Harmon's motion, Judge Steinkruger relied on *Lee v. State*, 1076 (Alaska 1973). *Lee* was a case involving possession of four balloons, three of which contained white powder. The state found one of the balloons and discovered it contained heroin. The state charged *Lee* with possession of heroin.

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WILLIAM DAUBERT, et ux., Individually and as Guardians ad Litem for
 JASON DAUBERT, et al., Petitioners

v

MERRELL DOW PHARMACEUTICALS, INC.

509 US —, 125 L Ed 2d 469, 113 S Ct 2786

[No. 92-102]

Argued March 30, 1993. Decided June 28, 1993.

Decision: "General acceptance" of principle underlying scientific evidence
 held not to be necessary precondition to admissibility of such evidence
 under Federal Rules of Evidence.

SUMMARY

A minor child and his parents, together with another minor child and his mother, brought suit in a California state court against a drug company which had marketed the prescription drug Bendectin. The plaintiffs alleged that the children's birth defects had been caused by the mothers' ingestion of Bendectin during pregnancy. The suit was removed, on diversity grounds, to the United States District Court for the Southern District of California. The company moved for summary judgment and submitted, in support of the motion, the affidavit of an epidemiologist to the effect that no published epidemiological (human statistical) study had demonstrated a statistically significant association between Bendectin and birth defects. In response, the plaintiffs offered expert opinion testimony based on (1) test-tube and live-animal studies that had allegedly found a link between Bendectin and birth defects; (2) pharmacological studies that allegedly showed similarities between the chemical structure of Bendectin and that of substances known to cause birth defects; and (3) the reanalysis, or recalculation, of previously published epidemiological studies. The District Court, granting summary judgment in favor of the company, expressed the view that (1) scientific evidence is admissible under the Federal Rules of Evidence only if the principle on which such evidence is based is sufficiently established to have general acceptance in the field to which it belongs; (2) epidemiological studies were the most reliable evidence of causation of birth defects; (3) the testimony based on test-tube, live-animal, and pharmacological studies was

inadmissible because such testimony was not based on epidemiological evidence; and (4) the testimony based on reanalyses was inadmissible because the reanalyses (a) apparently had never been published or subjected to peer review, and (b) failed to show a statistically significant association between Bendectin and birth defects (727 F Supp 570). The United States Court of Appeals for the Ninth Circuit, affirming on appeal, expressed the view that (1) expert opinion based on a scientific technique is inadmissible if the technique is not generally accepted as reliable in the relevant scientific community; and (2) under the general acceptance standard, the plaintiffs' evidence provided an insufficient foundation to allow admission of expert testimony that Bendectin caused birth defects (951 F2d 1128).

On certiorari, the United States Supreme Court vacated the Court of Appeals' judgment and remanded the case for further proceedings. In an opinion by BLACKMUN, J., expressing the unanimous view of the court as to holding 1 below, and joined by WHITE, O'CONNOR, SCALIA, KENNEDY, SOUTER, and THOMAS, JJ., as to holdings 2 and 3 below, it was held that (1) the "general acceptance" test of *Frye v United States* (1923) 54 App DC 46, 293 F 1013, 34 ALR 145, was superseded by the Federal Rules of Evidence (FRE), and thus general acceptance is not a necessary precondition to the admissibility of scientific evidence under the FRE, given that (a) nothing in the text of Rule 702 of the FRE, governing expert testimony, establishes general acceptance as an absolute prerequisite to admissibility, and (b) there is no indication that Rule 702 or the FRE as a whole were intended to incorporate a general acceptance standard; (2) under the FRE, a federal trial judge must insure that any and all scientific testimony or evidence is not only relevant but reliable; and (3) in a federal case involving scientific evidence, evidentiary reliability is based on scientific validity.

REHNQUIST, Ch. J., joined by STEVENS, J., concurring in part and dissenting in part, (1) agreed that (a) the *Frye* "general acceptance" rule did not survive the enactment of the FRE, and (b) Rule 702 of the FRE confides to the trial judge some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony; but (2) expressed the view that the Supreme Court should have left the further development of the area of the law in question to future cases.

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Hubert v. Netherland
125 L. Ed 2d 469:

files 702 & 703

Under ~~Fitz~~ v. US (1923), it was
held that expert scientific
testimony ~~has~~ to have been
subjected to a peer-review
process in order to be admitted.

Take out "technical" & after
"scientific"

It must be supported by
appropriate validation

POSSIBLE AMENDMENT TO ALASKA EVIDENCE RULE 702 IS IN
CAPITAL LETTERS:

Rule 702. Testimony by Experts

(a) 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. IT SHALL BE AN ABSOLUTE PREREQUISITE TO ADMISSIBILITY OF SCIENTIFIC AND TECHNICAL EVIDENCE THAT THE SCIENTIFIC TECHNIQUE, DISCOVERY OR PRINCIPLE ON WHICH SUCH EVIDENCE IS BASED IS SUFFICIENTLY ESTABLISHED TO HAVE GENERAL ACCEPTANCE IN THE FIELD TO WHICH IT BELONGS, INCLUDING VALIDATION BY PUBLICATION AND PEER REVIEW.

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BUSIN

Breast-implant trial opens

■ *First class-action trial is against Dow*

By JANET McCONNAUGHEY

ASSOCIATED PRESS

NEW ORLEANS — Lawyers for Dow Chemical Co. denied that the firm hid research indicating that silicone breast implants were dangerous, a claim made by the plaintiffs during opening arguments of the nation's first class-action trial concerning the implants.

Thousands of women say their implants leaked and caused illnesses, including arthritis, lupus and scleroderma.

Plaintiffs' attorney John O'Quinn said Thursday that Dow failed to test silicone enough to prove that it was safe to use in the body and hid tests indicating it was dangerous.

"This case is about ... values ... putting safety ahead of profit," he said.

Dow attorney Lorna Propes countered that Dow never hid anything and that Dow Corning Corp., which made the implants, relied on hundreds of studies that said silicone was safe. By the time Dow Corning began making breast implants in 1964, 236 published studies had reported that silicone was safe, she said.

After opening arguments Thursday, the trial recessed until

Dow attorney Lorna Propes said doctors have known since implants were first proposed that silicone could seep out through the plastic covering.

Wednesday morning.

The eight plaintiffs in this stage of the trial — the first in the country to win class-action status — represent at least 1,260 Louisiana women who claim that Dow implants leaked or ruptured, causing health problems. The plaintiffs have not specified how much they are seeking.

Most breast implant lawsuits were frozen when Dow Corning filed for bankruptcy protection. This one is going forward because the women sued Dow Chemical, which never made breast implants but owns half of Dow Corning, once the largest maker of silicone gel implants. Corning Inc. owns the other half.

Dow Chemical said that it never conducted any tests to see if silicone was safe for breast implants, and that Dow Corning contracted with other companies for the tests.

Propes said doctors have known since implants were first proposed that silicone could seep out through the plastic covering,

but that studies have shown that silicone does not cause diseases.

"You must be thinking, 'Then why are we here?'" she said. "The answer is lawsuit science. Litigation doctors ... make a fortune going around and testifying in breast implant cases."

Several manufacturers proposed a \$4.25 billion national settlement in 1994, with Dow Corning agreeing to pay \$2 billion. But the settlement collapsed last year.

Last week, a judge in Detroit dismissed claims brought by Michigan women, holding that Dow Chemical cannot be held responsible for possible ill effects of silicone breast implants. Dow Chemical also has been freed from breast implant claims in California and New York.

The judge split the case into separate trials. The trial that began Thursday is against Dow Chemical. Future trials are to be held against Bristol-Myers Squibb and Baxter Healthcare Corp. and 3M.

WELCOME TO THIS PROGRAM RECORDED AT THE 1997 NATIONAL LEADERSHIP CONFERENCE OF THE AMERICAN MEDICAL ASSOCIATION, WE JOIN OUR SESSION NOW AS IT BEGINS....

DR. CARLIN - ..."has taken this project in hand, because we are concerned as to what we see in the courtroom today. There are changes made, and we certain aspects and each of our panelists, are gonna talk on a different area on science. Ah, when you talk about or consider science in the courtroom you have to consider the jury. Does the jury really know the difference between good and bad science? You have have to fear the runaway juror, jury; and are their decisions based on emotions, sympathy, a sort of 'never mind the facts' situation; rather than on scientific evidence. 2.) The expert witness. He's paid, he's chosen. I think the expert witness has to be held accountable, by the local and state societies and specialty associations. 3.) The attorneys, we recognize are problems there - because they're actors. They get paid as long as that taxi meter keeps going; both the defense and the plaintiff. And, the plaintiff itself, we have problems these days because, according to the Harvard Study; it makes no difference whether the doctor has performed according to the standard of care. If there is a harm or a major disability or a handicap; the jury looks at that patient and will award runaway awards because they the sympathy to the patient; even though the doctor did not do anything that was below standard of care. They don't listen to scientific evidence. And, then the judge; Dr. Elliot will talk on this, but there's new laws after (mumble Dowberth merrill?) Dow where the judge now can interpret science on reliability and relevance; he can decide what is pertinent and what should come in scientifically. We have a breath of fresh air as to what just happened in Oregon and I know that Professor Elliot will talk on that. And of course we then get to the news media. They have significant liberty to do what ever they want to, just to create an outrage. At this time, there are 800 science and medical editors or reporters in the country. There are 12,500 radio and TV stations, and 1,650 daily newspapers. They're delighted to have anyone who is interested in science, who may be not qualified, give them a statement thta can change the scientific statement to something which they can interpret by layman's language, which they can then convert to a public pol - public opinion which then may go to a public policy. So, our job is to get in there and give them accurate information, but remember, the newspapers are very tempted to come out and outrage you. Get the initial report out; and never retract. And, I can give you case, after case, after case, but I'd rather listen to our panelists. So, let's get to our panelists because it leaves us our final problem; and that's the physician himself. And, I'm - sitting to my right I have three gentleman's. A rose and two thorns. Three panelists. They're all experts in their own area, um, I'm going to begin with the first general, ah, Mr. George Schloeder. George is an attorney, he's Vice President of risk management in Skippy. I should state that each of these

curriculum
vital?
?

panelists have curriculum vitae that are so long that I'm not going to read them; because each one of these individuals would qualify to compete for a position on the Council of Scientific Affairs. That's the highest honor I can give them. (laughter) But, George is a very gifted speaker, he's spoken on over 6 to 800 times on various areas of technology of medicine and science. Ah, he's an attorney and he brings a unique background. He is in charge of risk management for Skippy holdings and ah, George is like the general in the front line whose got his head turning, turned back to me all the time saying "where's my secret weapon, where are my reserves?". George is gonna tell you now what doctors do to themselves in the area of science and the liability issue. Dr. Schroeder...

DR. ROEDER - Thank you Dr. Carlin. Um, I do ah, hope that, ah, many of you know that the, the obviously the electronic world itself, the internet everything else has changed everything. I was happy this week at least to know, that of sodium of the later things that have come out - um, I did not before that the pain of circumcision lasts for life. (laughter) I will be speaking to you about representing me after this. (laughter) I've, I'm positive there was no disclosure prior to my consent (laughter). Um, the Hopkins method for controlling blood sugar, that the obviously sliding scale insulin is no longer effective and if I could remember to take ah, ibuprofen, I'd be better off. Um, tuna still has hidden sulfites; I, I nev- I always suspected those animals. And, that all skin problems are now linked to the ozone. So, given those issues I think that, that's that's where we come from. Um, so today we want to spend a little time with the issue of science in the courtroom. The physician perspective, sometime is a little bit different than the legal perspective or the pure science perspective. Keeping in mind that ah, the doctor has to to live in a real world. I'm always reminded though, at least of Robert Frost's great comment, and this is probably the wonderful time to say it; "the brain's a wonderful organ, it starts working the moment we wake up in the morning and does not stop we get into the office". Or, as lawyers say, until they begin to speak". Um, the problem with science here, is that in theory there's no difference between theory and practice. In practice however, there is (laughter) and, so we live in this world of quasi-science in a world that has real science. And, it creates, a, a human problem, a human experience problem, as well as clearly a courtroom issue problem. Couple of quick issues on the bottom line here; that set the stage I think for the discussions that relate to the legal side as well as the, the clinical or pure science side. I, I always look, as a risk manager to the areas of motivations; and I'm assuming the following fundamental motivations exist out there. That physicians have the desire to heal; they don't like to lose. And, in accomplishing that task, they have a desire to provide the latest options. Knowing what those options are sometimes are difficult. An efficacy is often times only know retrospectively. They also have a high desire to please; not like the two behavioralist who met passing on the street, um, 'I'm fine how are you?'. Um, the patient on the other hand, really has a desire to be well,

despite a lot of the population that we currently serve. They really have a desire to be well. They have a fear of not receiving the latest options. And, to that they turn to sources. Science and quasi-science. Television talk shows; to determine the best method of achieving the goals that they're looking for. Um, I've always believed that nowadays; at least in California, the patient are really straight forward, although we have a fairly extensive managed care background, the patient's desire now, is to be able to be able to walk into the office without the appointment. To bypass the front office, to bypass the back office, to walk into whatever exam room the physician is in, to excuse the patient that is there. Um, and to sit down and explain to the physician what their needs are, because they've seen it on television, know exactly what the tests should be done and where they need to go. They know what is the most effective study. But, in the meantime they would like to receive a single pill which is the definitive cure to the entire disease condition they have followed by an appropriate chaser; and then go on back to work. Um, that sometimes is an expectation mentality that we have to deal with that we create through the electronic medium of today. And we have this mixed approach to confrontation expressed by patients. First off to their issue of severity of their own illness, because everyone has a tendency to delay, for the most part; we have a large part of the population that will do it this way; a small subgroup obviously will respond a little quicker. But to severity; we have denial. And, we deny illness until we're afraid of serious consequence. At which point then we want all of the firehouse cleared to manage the problem and solve it; regardless of my own accountability or my own responsibility, in coming and working with someone early on. For example, wellness programs are for others. And, so also then, they have to deal nowadays with the fear of access, and they're afraid that high technology is not going to be available to them, or that it's going to be limited ah, in their ability to access it. And, so they confront based on that. I do point out a couple of constitutional guarantees that exist that relate to the first amendment, and now that we're in Philadelphia it's probably an appropriate topic. It's a little known fact that the initial draft of the first amendment was designed to guarantee the people the right to be stupid. (laughter) Um, this was removed from the constitutional text, but it has been subsequently added in case law. And, so the point that I raise is - science is in that same category; we think of it in the same light. Issues sometimes, for the most part are the issues of perception versus reality. (laughter) Um, I would very much like to look my 6'4 1/2", 160 lbs son, and so if any of you have gone to the weekend course and can take care of me this weekend, let me know. This concept of optimal care, and it is part of this whole basis of science that scares me. The dealing that I'm concerned about on this optimal care; and everybody talks about it, you know, that we've all gonna provide optimal care; but in all honesty optimal care represents to me that if I've got for example: a cardiac condition, then the best physician in the world have the facility in the world with the best staff in the world are going to take care of me on their best day when my condition is unchanged from

what the initial assessment was; then I'm compliant. Everything short of that is a compromise. And, it's amazing how much optimal care we believe we deliver out there. Or, how patients believe they want this concept of optimal. And it creates this tremendous gap for which, attorneys and the court system have to deal with; this expectation gap, this perceptual difference and how it was explained, which is the most important part of this. Coupled with that by the way, statistically it is absolutely true that 50% of the physicians in the world are below average. (pause) (laughter) True science says that 50% of the doctors have to be, below average. On the other hand, we, you know, to be fair - there are three types of lawyers in the world. Those who can count and those who can't. (laughter) The concept of communication becomes therefore the material by which the law becomes um, the presence for us; the issues that we have to deal with and it creates the biggest problem for the physician. In the doctor patient relationship clearly, language and the terminology differences pose significant problems. In the court room, in the scientific testimony, language again becomes a major issue. The process by which we incorporate or deal with that information, through selective hearing, what we think we heard and for those of you that have been married for a length of time - you understand this already. (laughter) Um, I for example; know my wife knows, when to ask, when to go shopping. It's normally in the middle of a football game. And the response normally is ... "I'm going to go shopping" - "yes, yes dear, whatever" you know.. and "I'm going to go buy a lot" "Okay dear, see you when you're back". I can stay totally focused to the Green Bay Packers (and since this is taped - I think it's appropriate) um, and, and create that selective hearing. Primary learning is going to be a larger problem in scientific evidence; now a days with the volume of information available to patients, to read, prior to even talking to the physician; they will have established a primary learning base which now educators know they have to overcome; the physician must overcome in the discussion. And, if it's not incorporated significantly with that primary base - they're back to selective hearing. We have to recognize that, that creates part of this distinct problem. The time constraints of disclosure, clearly in the doctor / patient relationship are also of issue.

Communication solution was simply; Albert Einstein (sic) said it best "everything should be explained as simple as possible, but not simpler. but, sometimes when we try to deal with things scientifically; we deal with difficult issues. I'd like as a group; think about it for a minute, I want you; be a scientific expert testifying as to certain terms the doctors may have used in discussing ah, procedures or efficacy. It's pretty easy for us to look at something that happens half the time; if you signed a percentage to that, that's 50%. Often- here's a word: "frequently" - what percentage is frequently? What percentage is "seldom" , what percentage is "rare complications", what percentage is a remote complication. And, again, if we deal with that difference in the expectation between the doctor and the patient (and that's not clearly communicated), that's an issue. And finally

- "ocasionally"; I like occassionally; goes along with other words we see physicians write like, mystically, that occur in the records. Um, but, we see this terminology trying to explain scientific issues. But we live in this world in which, lotto, the lottery is a very important component. When the lottery hit (whatever it was) 113 million dollars in california, they explained scientifically; in clear terms, what my odds were of being the sole winner. And, the explanation was that i was more likely to be struck by lightening 11 times, than to win that lottery. So, I bought twenty bucks worth of tickets. (laughter)

Number 190

The jury of your peers. Now, we're setting the tone for the discussion to follow. Alright, we start with a pool of 150 people - who can't get outta jury duty. (laughter) And, they have no preconcieved ideas of: medicine, physicians, or science. They all avow the following: they don't watch television, they don't listen to the radio, they don't read the newspaper or books, they are going to be fair and impartial and they're willing to wait until all evidence is in, prior to making a decision. That is what you're faced with when we talk about the jury pool; our typical juror is the one we hopefully has come out of theier cave in Hemmett, California and is there to you know, render the opinion.

Number 201

The physicians world. The reality of a doctor/patient relationship is based on human science. Inaccurate at best. Decissions are based upon - 'reasonable foresight, within an active day', and, they changed from day to day and knowledge base to knowledge base. In the courtroom it is the perception of the science or evidence which prevails; not the science or the truth; And as much as we'lll talk about that today it is the basis of the physicians frustration. That we are dealling with perceptual realities despite all of the things we would like to do tort reform wise, we are still going to deal with this fundemental issue. And, no matter how we attempt to reconcile or control this incongruity, this rift will always be present and will shape or attitudes. To me, this is the core basis of where the physician comes from in trying to deal lwith science. Not, dealing so much with the issue of the phony expert, or the expert or the expert that has testified over time. The issue is - how do I apply this to my practice, with my patient; because it is medicine that i am involved in and not the law.

Number 223

I just love Yogi Beara; yuou can observe alot just by watching. Yogi was always profound. With that, I'd like to introduce Professore Elliot who will

be here to talk about the courts and the system behind it. (lots laughter lots of clapping)

NUMBER 233

DR. Carlton? - I would like everyone to take a look at David Netzer who's standing right over there, and George Roeder; this is our example of our first clone in the United States. I'm not sure we had the right speaker. But, George thank you. May I ask you a favor, if you'll please move down if you can, cause people are coming in and they don't see any seats, now for those of you who are standing, we do have seats up here and it'll help us if we can move in, cause they're coming in and they're seeing that the place is packed and they tend to leave. Thank you.

Number 254

DR. CARLTON? - I think we'll move the agenda, ah, our next speaker (because of what George did) will not be professor Elliot. (laughter) I'm gonna save him for last. Ah, our next speaker is very well known - Marcia Angel, ah is the Executive Editor of the New England Journal of Medicine and she's a lecturer in the Department of Social Medicine at Harvard Medical School. She has an extensive curriculum VEETI? again, as i stated, but you all know Marcia and you know that she is a physician, she's an internist, she's ah, certified in anatomic pathology. The onlyl thing; it was interesting to me, even though I've noticed she's an author and a co - author and she's written extensively was, and as i've told her before; one thing just struck me is that she had a Full Bright Scholarship at the ~~Goothe/ Gurthey?~~ University in Frankfurt Germany. And, of all the things I've read it just brought back memories to me because, when i was in college, i was the candidate for the Rhodes Scholarship and I competed in Ohio and the, ah, one of the persons who interviewed my said - "Dr. ah Mr. Carlin um, what american communists have you read?" (You've ggot to understand my whole thrusts and priority was in pre-med, that's all I read.) And, i said - um, um, "Gurthe" (sp) And he said "Gurthe is German", and I said " yes sir, but he's american read". (laughter) And, so i just enjoyed noticing her; that she's had an extensive backround, everything that Marcia writes, I love reading about and particularly her position on the breast implants senario; as you know those of us on the coucil on scientific affairs have taken a very strong position there. We've come out with 13, with 3 articles already, ah on this issue. We're going to be coming out with a fourth article this June on Silicon Elastermers Shuntz on cerebral spinal ~~flow~~ shunz systems(?). It's highly supporting it with one comment in here that i think i should read to you: "at this time there is no suitable replacement material that exists at this time" you want to usse materials that are effective and you're gonna save lives; you've gotta

Goethe

shuntz

use what we have and so far the AMA has really taken a strong position here. Marcia I don't want to take any of your thunder - please.... (clap)

Number 297

DR. MARCIA ANGEL Thank you very much. It's a great pleasure to have been asked to speak with you this morning. I'm going to be talking about the controversy over silicone gel filled breast implants. As an example, of the larger disconnect between the way a scientific question is approached by scientists and the way the same question is dealt with in the court room. And, make no mistake about it, whether, breast implants cause disease, is a scientific question. I thought I'd begin by telling you a little bit about how I became involved in this controversy - so my talk will be something like the 'venerable children's essay' every fall when they write "how I spent my summer vacation". I'm going to be telling you how I spent my mini sabbatical. In 1995, after 16 years at the New England Journal of Medicine - and I realized, with a profound sense of fatigue, that that's 832 weekly issues; I found myself first in line for a newly created mini-sabbatical, four month sabbatical. The only condition for taking this sabbatical is that I spend it, on a project that had something to do with my work at the Journal. After about a micro second of thought - I decided that I would spend it investigating the breast implant controversy. And, the result was a book that I published in June of last year. It was published by W.W. Norton, called "Science on Trial: The Clash of Medical Evidence & the Law in the Breast Implant Case". Now, if I had been told just a few short years ago, that I would be spending this precious first; and perhaps last; four month sabbatical writing about breast implants, I would've been astonished. I had no interest in this subject. There wasn't any research done on it and what there was, there was maybe a little bit; wasn't very good. Certainly the New England Journal of Medicine had never published anything on the subject before 1992. So, why did I then decide to spend my mini-sabbatical writing about breast implants? It all began in 1992, when Commissioner David Kessler banned Silicon Gel Filled Breast Implants from the market, not because they were dangerous, he was careful to say, but because the manufacturers had not fulfilled their obligation to show that they were safe. Shortly after the ban, he submitted an article to the New England Journal of Medicine, in which he described his rationale for having withdrawn the devices from the market. At the time of the ban, in early 1992, Kessler was certainly right about one thing, there was no evidence whatsoever, no credible evidence that breast implants were either safe or dangerous. There simply hadn't been any good research on the subject. There had been some anecdotes in the literature, beginning in the early '80's. Anecdotes of women who had breast implants; who later came down with disease usually connective tissue disease; scleroderma, lupis, rheumatoid arthritis but anecdotes are not evidence. Kessler in the piece he wrote for the New England Journal of Medicine said that the "decision had been a difficult one, he could've gone either way. " Afterall, breast implants had been

available for almost 30 years at the time of the ban; and there was no particular reason to think that they were dangerous. About 1 million american women, had breast implants; that is about 1% of the adult female population. And, Kessler realized that when he banned the implants it would be of great concern to these women who had them. In the same issue of the Journal that Kessler's article was published, I wrote an editorial to accompany it in which i said that i understood his difficulties but i thought he had made the wrong decision; that the ban would be unnecessarily alarming to the 1 million or so women who already had breast implants. And, indeed the ban was alarming. The women who had the implants couldn't be expected to read his fine print. They didn't realize that the ban was because the manufacturers hadn't shown that they were safe; ; instead quite naturally, women assumed that breast implants had been banned because the FDA had found that they were dangerous, and so many women went to their plastic surgeons to have the implants removed. A couple of women who felt that they could not afford the plastic surgeons fees were so desperate that they actually tried to carve out the breast implants with razor blades. That's a measure of how frightened many women were. And, many women went to court. In general, at that time the stories in the media and public opinion took it as a given that breast implants were dangerous. This premise was seldom questioned. The trial of law suits that had been going on, it goes on with any devices, over the '80's, almost overnight after the ban became a tidal wave. Dow Corning which made about half of the implants; had been the target of roughly 200 lawsuits at the end of 1991. But, in 1992 the year of the ban, suddenly it exploded to 10,000 lawsuits in that year alone, and the following year there was another ten thousand. Now, each of these 20,000 lawsuits had to be dealt with. They had to be settled, they had to be fought; and the expense, obviously mounted up. Using a very conservative figure of 10,000 dollars to settle or defend or otherwise deal with each of these lawsuits. You can see right there, that it would be 200 million, even if Dow Corning won every single one of them - but in fact it didn't win everyone of them. There were some astonishing jury verdicts on, for plaintiffs in these cases. The largest was a case in Houston, in which the jury awarded the women 125 million dollars. END OF TAPE

TAPE 1, SIDE B
Number 029

DR. ANGEL - (undecernable) ...verdict, of course drove up the cost of settling out of court, so, that in Texas, it was said that the average out court settlement was on the order of a million dollars. Naturally, the breast implant manufacturers were desperate to stop this hemorrhage, and so in April of 1994; that's two years after the ban, the major breast implant manufacturers agreed to the largest class action, in history, class action settlement rather, in history. 4.25 billion dollars to be awarded to everyone women with breast implants, who claimed that the implants had caused her to become ill, or

who became ill in the next 30 yrs. (laughter) It wasn't until June of 1994, two months after the class action settlement was announced; and a full two years after the ban, that the first rigorous scientific study of whether breast implants, in fact, do cause disease in the rest of the body, was published. That was a study, that was performed at the Mayo Clinic and published in The New England Journal of Medicine, June 16, 1994. This study could find no link between breast implants and twelve connective tissue diseases, ten signs and symptoms suggestive of such diseases, and 4 abnormal laboratory tests, suggestive of such diseases. In the same issue of the Journal; that the Mayo Clinic study was published, I published my second editorial, on this subject. In that editorial I pointed out this backward sequence of events. I mean, here we had the public opinion, followed by the ban, followed by multiple lawsuits, followed by the largest class action settlement in history; and only, after all of this had happened, did we have the first scientific evidence published. In this editorial, I speculated as to why this sequence of events had been backwards; one would expect the evidence first, and then the regulatory and legal activity, and I pointed to some of the peculiar characteristics of the American court system. No sooner had the Mayo Clinic study been published and my editorial, then I found myself the target of allegations by plaintiff's attorney's that I had been paid by the breast implant manufacturer's to publish the Mayo Clinic Study, and to publish the editorial. Over the following year I received two subpoenas from plaintiff's attorneys asking for all documents showing communication between the breast implant manufacturers and myself; all payments, records of payments from them to me; all records of payments by them, for media training that I, had received. Now, it would have been easy to respond to these subpoenas because, there were no such documents. I had never had ANY contact with breast implant manufacturers; but, the subpoenas also demanded that I produce the Journal's internal records of peer review of the Mayo Clinic Study, and that, I simply could not do. The Massachusetts Medical Society, which owns The New England Journal was extraordinarily supportive; they immediately filed a motion to quash the subpoena, and they were ultimately successful. I was then, the target of another subpoena, asking for essentially the same things, and again the Mass. Medical Society filed a motion to quash, and again it was successful. Now by this time of course, I was very interested in the breast implant controversy (laughter), and that's why I spent my mini sabbatical, writing the book that I wrote.

Number 080

DR. ANGEL- The implications of the breast implant controversy go way beyond the question of whether breast implants cause disease; important though that question is; and what I'd like to do in the remaining time, is to briefly tell you what I think some of these important implications are.

c f (c)

First, the breast implant controversy exposes a runaway tort system that is able to engage in the shenanigans that are still going on because of some peculiar features that distinguish our tort system, from almost any other tort system in the world. First, unlike any other system, we pay plaintiff's attorney's contingency fees; you all know that; they get a percentage of whatever they get for their client; if they get alot, they get alot, if they get nothing, they get nothing. This situation is an incentive for plaintiff's attorney's to engage in a certain lottery feeling; in which, in the case of mass torts; like the breast implant controversy is; that is, multiple women alleging the same thing. In these cases, the plaintiff's attorneys have an incentive to invest heavily, in building a case and then going out and soliciting clients to fit that case. They're now building a case against Norplant; which also contains silicone, and against testicular implants which also contain silicon. In the breast implant case, ah, the 25 million dollar verdict that I mentioned; the attorney was entitled to 40%; that's ten million dollars right there. So, you can see that in this lottery system, a major win like this, can subsidize quite a few losses. The idea is to get as many cases as possible, to fit your case.

Number 108

R82

DR. ANGEL: Second, in our system, the defendant pays; no matter who wins. So, as I mentioned before, Dow Corning faced enormous costs, even if it won every case; in defending them. Third, unlike any other country in the world; we try tort cases in front of juries. Most tort cases involve technical, expert testimony, which, despite all of the celebration of the great american jury; juries are simply competent to evaluate; and so juries vote with their heart, they respond emotionally to the plaintiff, and to the performance abilities of the two lawyers. In product liability cases; such as the breast implant case; they see on the one hand a plaintiff, who may be appealing; maybe very ill; and on the other hand, this plaintiff is against a large, impersonal, rich corporation. Well, what do you think the juries do; they have a 'robin hood' feeling, they want to even things up and they do. Fourth, and most important in my view; is the peculiar way that we use expert witnesses, in the american tort system. The experts - are chosen, by both sides, they're paid by the adversaries, they're rehearsed in advance, and they in fact are selected to give biased testimony; that's the whole point. Nor, do they have to base they're testimony on any scientific literature, any scientific study, in the scientific peer reviewed literature. Recently, since the 1993 U.S. Supreme Court Dawbert decision, judges are suppose; federal judges are suppose to decide in advance, whether the expert testimony meets the criteria of relevance and reliability. The judges, aren't a great deal better, at evaluating scientific evidence than juries; they're not trained to do this either. And so, even since Dawbert, the reliability and relevance criteria have been honored, many in the breach. I believe the the greatest, single reform, of this system would be if judges were to exercise they're option of calling neutral witnesses for the court, to help them, in evaluating the scientific

evidence produced by both sides. Now, judges have the option of doing this; but they don't. They rarely do it, I think primarily because they are ideologically committed to the adversarial system; as a way to answer all questions, even scientific questions.

Number 152

A second implication of the breast implant controversy, is the message that it is sending to the medical device industry. Breast implants aren't the only devices that contain silicone, Norplant as I mentioned contain silicone, testicular penile implants, and vital devices; heart valves, artificial heart valves, artificial joints, dialysis tubing, hydrocephalus shuntz, all of these, contain silicone; and, what happened to the breast implant industry could happen to these manufactures, as well. It can also happen to non-silicone containing medical devices, and to the suppliers of raw material who, according to United States law, can be held equally viable; even for devices that they had no part in designing and manufacturing. For this reason, DuPont has announced that it will no longer supply Dacron Polyester, to manufactures of vascular grafts. For Dupont, this isn't a big part of their business; they can well pull out of this market. For the manufacturers of vascular grafts, of course, it's devastating.

Number 169

DR. ANGEL - A third implication of the breast implant controversy, is the fact that researchers, doing work that plaintiff's attorneys don't like; can be harassed by subpoenas, until they stop doing their scientific work. Not only was I the target of subpoenas from plaintiff's attorneys, but the Mayo Clinic was too; shortly after we published their study. The Mayo Clinic, as I'm sure you all know; has, houses and and invaluable data base, they have been keeping data on everyone in Olmstead County; where the Mayo Clinic is located, since 1907. The plaintiff's attorney's subpoenaed, not only the raw data of the breast implant study, but the entire data base. This threatened the very existence of that data base. Doctors who help, by admitting patients, and allowing them to be in the data base, threatened to pull out of the data base, because they couldn't guarantee the confidentiality of the their patients. For this reason, the Mayo Clinic, instituted a moratorium on all further work on breast implants. This of course, is exactly what the plaintiff's attorneys wanted - no research; and the Mayo clinic has felt it necessary to do this. Where do we stand now? Well, the class action settlement; enormous though it was, collapsed. It simply wasn't big enough to cover all of the women who registered for it. A new class action settlement, has been crafted together, involving the three remaining large manufactures; Dow Corning filed for bankruptcy protection, so that's out. The three remaining large manufacturers agreed to another class action settlement, with slightly more stringent conditions, less generous compensation, whether that holds up,

remains to be seen.

Since the mayo clinic study, there have been approximately ten, well designed, good studies, looking at the question of whether breast implants cause disease in the rest of the body. Not one of them, has been able to find evidence, of a link between breast implants and diseases in the rest of the body.

Number 208

DR. ANGEL - Individual suits are still going to court, ah the tide, seems to be changing; the defendants are winning the great majority of them, but the plaintiff's are still winning an occassional multi-million dollar suit. The most encouraging, the most important change, in my view, is that three federal judges, have in fact, decided to appoint neutral scientist, to help them evaluate the evidence on both sides. One of these judges is Judge Sam Pointer, he is the Alabama, Federal District Judge who is overseeing the national class action; he's appointed a panel. Another one is, Judge Jack Weinstien; very inflential Judge in New York, who has appointed a panel, and a third is Judge Robert Jones, a federal district judge in Oregon, who had about 70 breast implant cases before him, he appointed an expert panel to help him evaluate the scientific evidence on both sides. On the basis, of the evaluation given to him by his four experts, last december, he threw out all of the plaintiff's expert testimony. No case. To me this an extremely important, a stunning blow for sanity and i hope, the harbinger of things to come. There are signs then, that this particular mass tort, has seen it's high water mark. I hope we've learned something from it, particulary about the risks of trying to answer a scientific question, in the absense of evidence. But I'm not sanguined because there are alot more lawyers in this country than there are doctors. There was a man in San Fransicsco who tried to do something about that, and I'll finish by telling you his story.

Number 240

DR> ANGEL - He was a tourist in San Fansisco and he was having a wonderfful time one weekend, going up and down the hills and looking in all the little shops; and he went into one curio shop and there he saw the most perfect little statute, of a rat. The rat looked almost alive, it had bright, glistening, beedy little black eyes, each wisker was carefully sculpted. You could almost feel the fur on the rat; and the tourist had to have this rat. He went to the shopkeeper and he said, "how much for this wonderful little rat", and the shopkeeper said, "the rat is \$2000 dollars and for another \$1000, you can get alittle pamphlet that tells you the story of the rat. The tourist said, "I don't want the pamphlet, you can keep the pamphlet, but i've gotta have the rat, don't bother wrapping it; I'll just take it with me", and he paid the \$2000 and he went out of the shop, and he started down toward the waterfdront. As he was walking along carrying this rat, he heard alittle scrabbling noise

behind him, and he looked over his shoulder, and there was a real rat, following him along on the sidewalk. A little while later he heard more scrabbling, turned around, looked over his sholder, three or four other rats scurrying behing him on the sidewalk. The tourist walked faster, more scrabbling, and then he noticed that rats were pouring out of the alleys and the side streets, and all following him; pretty soon he was running and there were hundreds, thousands of rats followiing him. He raced down to the waterfront, he threw the statute into San Fransico Bay all of the rats leapt into the Bay and drowned. He stood there for a moment ca'tching his breath, took out his hankerchief, wiped the sweat off his face, thought; turned around, trudged back up the hill, back into the curio shop. Shopkeeper says "ah, you've come for the pamphlet", "No, he says, still don't want the pamphlet, what I have come for though, is to ask whether maybe by any chance you have a little statute of a lawyer?" (laughter) Thanks very much.

Number 276

DR. CARLIN - When we last heard, ah, thank you Marcia. When we last heard Professor Elliot's name mentioned, we saw three, four sharks coming accross on the screen, and with that um, i'd like to ah, kinda nuetralize that picture by stating that Professor Elliot is a tenured Professor at the number one law shcool in the country

TAPE 2, SIDE A

WE CONTINUE WITH SIDE 3 OF OUR PROGRAM

DR. ELLIOT - I hope in some sense; at least indirectly, ah, that, that maybe some of those ideas are, are getting through. Ah, the notion is, that we shouldn't be able to mislead jurors about the scientific evidence, and one of the problems that we have in the current court system, um, is that jurors are not able to evaluate ah, between the two contending experts; who often are actually saying pretty much the same thing, but in terms of the way the questions are presented, makes it appear that they're ah, much farther apart than they really are. And, what typically happens in situations where, where people, this as ah, an academic theory called partisan mutual adjustment that was invented by ah, um, a political scientist named Charles Lindbloom. What he said is, when you've got a situation of pervasive uncertainty; which often happens in politics or law; what people typically do is define their position, not in terms of the underlying merits, but in terms of their relative position to someone else; so somebody in congress ah, who doesn't know how to vote on a particular issue will say, well tell me how Newt Gingrich is voting, and then I'll either know if I'm for it or against it, cause I know how I feel about, about newt Gingrich. The same thing tends to happen with juries; when you present in the adversary system two experts; one who appears to be saying white, one who appears to saying black; what's the jury likely to do? Well, depends a little bit on how the jury feels. If they hate corporations, they're going to go, gonna go with the black; but, most jurors tend to split the difference. Now the problem, with the tendency of jurors and a condition of pervasive ignorance to split the difference, is it creates an incentive to hire more and more extreme experts. And, one of the things that I admire greatly about Marcia's work; and we didn't get into it today, is she among, I think uniquely, among the scientific critics of the system, understands the economics of the system and understands that the economics are really driving it. Were not gonna fix this system, until we deal with the underlying economic incentives; and that's why my article is called: Tort Incentive Based Procedure. You have to understand though, what happened in the breast implant cases, is the trial lawyers who, who, I think would perpetuated this fraud, ah that's probably a little strong; ended up with a billion dollars. A billion dollars, to the group that brought those kinds of cases. That's a pretty strong economic incentive. Ah, and in the long run, you're not gonna get away from having this kind of ah, situation take place; unless you deal with some of those underlying ah, incentives. What we're talking about two different kinds of legal issues here. One is the types of malpractice cases that touch all of you, ah, directly that George referred to; I'm not going to spend a lot of time on that; but there is a legal reform strategy to deal with those. Um, and it's called contracting around the problem. When you have an irrational legal system, um we do, and, and, ah, ah, a economist named Raul Coos got the Nobel prize for pointing out the basic strategy of contracting

around an irrational governmental system. We can, through a series of contractual arrangements, substitute other fair remedies for the malpractice remedy. And, I mean, by that, an arbitration remedy, or schedules of damages; and this is a way, if you don't want to have you're, um, your work evaluated in the morality play context, ah, there is a, there is a an available technique in terms of contracting around that, ah, ah around that system. But, turning to the larger one, of products liability, and what we're doing in the , ah, in the expert area. There has been a response ah, and, I think the situation is somewhat better. Ah, the dauber decision decided by the supreme court in 1993, ah, is the governing law in the courts today. It is an approach which I called in my article, which proceeded dowber, ah, the screening approach, it basically posits that - ah, scientifically illiterate judges are gonna be gate keepers, and are gonna basically be able to decide which experts are testifying; in terms of valid science and which, are not; I was, I was skeptical about how much that would work in the, in the long run. The basic questions that it asked are whether or not the methods that are used, are generally accepted in the relevant scientific community. There's also a second level of questions about the fit between the scientific ah, evidence, and the, the issues in the case. I think that's helpful to some extent, and I would not be, ah, I would not be against it; but um, as I indicated in the article, I think a much more ah, useful and in the long run, much more successful strategy is one of using independent court appointed panels of experts to deal with the ah, to deal with the issues. We actually have a fair amount of experience with that, in the United States and it works remarkably well. There's a 1985 study by Professor Peter Baryth, ah at, at Connecticut, talking about ah, panel of independently appointed experts in, in workers comp cases, in Connecticut. Um, and what it shows is - there was a high degree of acceptability, um and perceived fairness, by both plaintiff's and defendants in that system. So it isn't as if don't have any successful models; we have some very successful models; the problem is that in that kind of system; people don't end up with a billion dollars in legal fees. So, it's got to be, professional societies like ah, like this one that are essentially advocating a better and fairer system. Well let me turn then, in the just few remaining minutes to the kinds of things that ah, professional societies can do to try to move us more in the direction that I think we all think, we should go. The first is ah, is one that was already mentioned, um a code of discipline. I'm a little skeptical about this idea because I think it's very difficult to set and enforce ah, ethical codes for your members that deal with the, the merits of what they testify about. Um, I think a better version of the same thing is again to get at the underlying economics. And I think you should consider whether or not it's possible to set some kind of ah, ah, code that attempts to regulate the economics of people testifying as professional expert witnesses. Ah, this is something that's actually been done, ah, many law schools or other university faculties have limits on the amount of inside consulting income that people can ah; just to prevent their judgment from being ah, ah too much affected by the economics. I know somebody will say - "well what

about regulating lawyers?", there are actually a couple of states that do regulate, the amount that lawyers can charge for contingency fees, New York does, for example. So, I think that there's a lot that can be done, ah in regulating the underlying ah, economics of the thing.

A second, and very important measure that can be taken; is to provide a source of independent experts. Um, my article is the beginning of a long, story for me about trying to get more independent experts used in the federal courts. This is an idea that came from an article written by my colleague John Langbine about the German advantage in civil procedure; which is cited in footnote 69 in my article. And he really talks about how this is done in Germany, and the German a word for this is great: "sakforshtendiga" - "those who understand the thing", um as the word for expert in German; it tells you something about their, ah approach, but in Germany, rather than having adversarial experts, the court appoints the expert in the first instance and the court gets the expert from professional societies. Um, and, and that I think is a far better system. So I tried to promote that; John and I held a conference in 1985 for federal judges and we tried to promote that. And as part of that, we did a survey of the federal judges and about 80% of them said that they thought neutral court appointed experts were a good idea, but fewer than 5% of them said they'd ever done it. Although that was kind of a disparity, so we tried to look at what was causing that and we did a follow up study with federal judicial center and the number one reason, ah that they didn't appoint court appointed experts is they didn't; know how to find them. They were concerned... that they didn't know how to find a neutral expert in these subjects, so that led to a recommendation in the Carnegie Commission Task Force, that professional societies in the United States, take on a role of being willing to provide neutral experts that are willing to testify; if they are court appointed. Um, and that in turn has led to um, an independent experiment by the American Academy of Arts & Sciences; the triple AS, the American Academy for the Advancement of Science and the federal Judicial Center, to work with professional societies to provide names of independent ah, experts, to try to help the judges. Ah, and I would suggest that The American Medical Association should be participating in that.

Um, the third and last recommendation, which I think in some ways is the most important one. Is, I think it's crucial for professional societies like the AMA, to participate in the public dialogue that is currently ongoing, um, in the courts. And I mean by that, by filing the meekest briefs as an organization. So much of what happens in these cases is really tainted by the adversary system of plaintiff's on one side, um, and, and, defendant on the other side; both of whom have an obvious ax to grind on the issue, of scientific expertise. And, for the same reasons that, we need independent scientific experts, we also need independent bodies that don't have an ax to grind, coming in and counseling the judges and speaking to the issues of scientific independence and reliability of expert ah, testimony. I've done that in cases in the past, I filed aamicus brief in the baby M, surrogate mother case, just dealing with some of the scientific evidence. Um, and I think it

would be... and, other professional societies have done that in the past; the American Psychiatric Association for years had a very valuable of participating in , in cases. But I think that's something concrete that this could do, with that I'll sit down and we'll have, we'll have; I'm sure we'll get into a very lively discussion in the question and answer session. (clapping)

DR> CARLIN - Befor we open the ah, audience to questions and answers, I did want to mention one case of an expert that ah, testified in ah, Los Angeles