LANDMARK LEGAL CASES IN SCIENCE BY RONNEE YASHON

Landmark Legal Cases in Science TABLE OF CONTENTS

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INTRODUCTION

This book contains eight legal cases. These cases are referred to as landmark cases showing how important they are in the legal system.

Many legal decisions made are based on precedent. Barron's Law Dictionary defines precedent as " a previously decided case that is recognized as authority for the disposition of future cases."

Cases previously decided by other courts in the state, higher courts or, finally, the Supreme Court of the United States, are to be used as "law" when subsequent cases are being decided. As an example take DNA forensics. Once a court in a specific state has accepted DNA forensics as admissible, any other case can use this decision as precedent and the argument for or against DNA forensics doesn't have to be made again.

The "landmark" cases presented in this book are considered the highest of precedent cases. They have made legal history and are used in hundreds of cases to prove points. The one thing they have in common is science and their relation to science cases.

Originally science didn't make its way into everyday life very often. Only scientists and physicians read journals and the public only came in contact with scientific fact when they were personally effected. Today, however, science bombards us from everywhere and courts are no exception. As everything from frozen embryos to the rights of those medically "brain dead" are decided in court, and our laws begin to regulate science, these decisions become very important. We need to know and understand these landmark cases.

As we move into the future, more and more science will present itself in the courts. As the individual decisions made in everyday life become more and more difficult, courts will have to step in to make these decisions easier. Understanding these landmark cases and their background, will help us to understand the future as well.

LEGAL BASICS

In general, legal cases are of two types: Criminal and Civil. In criminal cases science is usually introduced as part of the evidence. Some examples are DNA forensics, fingerprints and autopsy results. A criminal case usually results in a conviction or acquittal. When a defendant is convicted he or she will receive jail time or something similar.

Civil cases (tort cases) are different. These cases are one person suing another for a wrong, either intentional or because of negligence. The result of a successful civil case is usually an amount of money, called damages, given to the plaintiff by the defendant.

Some civil cases have a number of plaintiffs suing one defendant (called class action suits). These have much larger damages (sometimes in the millions) and can effect litigation for many years to come.

Courts:

Most states have three types of courts: trial courts, appeals courts and supreme courts (in some states the names are slightly different).

In criminal cases, because of double jeopardy, most cases are not appealed. If a defendant is found guilty, he or she cannot appeal unless there is an error in the trial proceedings. If a defendant is found not guilty, he or she cannot be tried again, under double jeopardy.

In Civil cases, however, the appeals process is different. If any person, either the plaintiff or defendant, is not happy with the result they can appeal to a higher court. This is what has happened in many of the cases presented here. If an appellate court or a supreme court did not take a case, the original result would hold.

How to Read a Legal Cite:

In this book, legal cases are cited by using the following notation:

19 Cal Rpt 494 (1993)

volume what book and state found in page number year

Sometimes a number of states are bound in a single volume... this is indicated by using an area as indicator such as, SO (south) or NW 2d.

Some states have their own volumes such as California and New York...ex: NY 2d...etc.

Cases heard by the Supreme Court of the United States indicate such by adding US to either their cite or the title of their case. In <u>Frye v US</u>, however the US indicates that the case was heard in the Washington, DC jurisdiction, which is not a state.

<u>Frye v US</u> 293 F 1013 (1923)

James Alphonso Frye was on trial for murder. He maintained his innocence from the time of his arrest. Early on, his attorney suggested that he take a test to determine whether he was telling the truth. The test was called "systolic blood pressure deception test", an early version of the lie detector used today.

The court was asked to accept his "truthful" results as evidence to support his plea of innocence. The technique was very new but his attorney had an expert witness. William Marston, an attorney and psychologist, was well qualified. He had done a great deal of research on how changes in the body's physiology correlates to lying. He claimed that the test measured whether the defendant was telling the truth by monitoring his systolic blood pressure*. The systolic blood pressure goes up and down depending on how hard the ventricles of the heart are contracting.

Mr. Marston said that fear always produces a rise in systolic blood pressure and lying, along with fear of detection, raises the blood pressure.

The judge of the trial court in the District of Columbia, excluded Mr. Marston's testimony stating that the science of "deception testing" is too new to be admitted. Mr. Frye's lawyer took the case to the Court of Appeals of the District of Columbia.

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^{*} In blood pressure readings, the systolic blood pressure is the upper number (such as 120/80) and indicates how hard the ventricles of the heart are contracting.

RESULTS Frye v US

The Appellate Court ruled that the "systolic blood pressure deception test" had "not gained standing and scientific recognition", therefore, upheld the lower courts decision not to admit Mr. Marston's testimony.

More important, however, the court set guidelines for other courts on admitting new scientific evidence. This standard, with a few exceptions, has been upheld in all states for almost 60 years.

The ruling stated that a scientific principle would have to have gained "general acceptance" in the "particular field to which it belongs". The so-called "general acceptance rule" had three parts. It asked the following questions:

- 1. To which scientific field does the evidence or testimony belong?
- 2. Is the evidence or testimony generally accepted in this field?
- 3. What constitutes general acceptance?

The scientific testimony must be scrutinized by a relevant scientific community and be significantly tested.

Soon after this appeal, another man confessed to the crime that the early polygraph said Frye did not commit.

After <u>Frye</u>, courts held what are called "<u>Frye</u> hearings" outside the presence of the jury to determine if scientific evidence should be admitted. As an example in <u>People v Castro</u> (545 NY 52d 985 (1989)), a 12 week hearing was presented in order that experts on DNA forensics could be presented to the judge. That hearing generated 5000 pages of transcript. The judge ruled that DNA evidence was scientifically "generally accepted" and therefore could be admitted. This was the first time a court in the United States admitted DNA evidence.

ISSUES Frye v US

<u>Frye</u> was a far reaching decision. Up until 1993 most courts used the <u>Frye</u> questions to determine if scientific evidence would be admissible in a trial.

<u>Frye</u> hearings, arguments for and against such evidence, were held without the jury present and the admissibility was determined by the judge. Experts testified as to the "general acceptance" of the evidence or technique.

Alternative to the <u>Frye</u> test, some courts (Federal) used a test called the relevancy tests. In this test, courts can admit testimony that is generally relevant to the case at hand. This was less confining than <u>Frye</u>.

More Recent Decisions:

In 1993, the Supreme Court ruled in <u>Daubert v Dow Chemical</u> that judges needed to take a more active role in determining which scientific evidence is admitted. In a "friend of the court" brief a group of Harvard University scientists said that good science is NOT equal and that every "generally accepted" scientific theory was once looked at as "junk science."

The Court increased the judges role in what would be admitted and called for the judges to be "gatekeepers" to be sure that "all scientific testimony or evidence admitted is not only relevant but reliable."

In <u>Joiner v GE</u>, the Supreme Court upheld this ruling. Mr. Joiner claimed he contracted cancer from working around chemicals. The trial court had decided that two scientific expert's testimonies were not acceptable and the appellate court reversed. But the Supreme Court said that the trial court was correct and had the authority to make its own decisions. Therefore, upholding <u>Daubert</u>.

Recently, in 1997, a judge in Oregon, deciding a class action suit on the silicon breast implants, made a ground breaking decision. He was afraid that too much expert testimony would put the jury to sleep, so he put a panel of experts together and asked them to study the science and report back to him.

SCIENCE Frye v US

Some interesting cases that have used the Frye ruling to determine relevancy of scientific evidence:

case	science	accepted?
<u>US v Tranowksi (</u> 1981)¹	analysis of shadow length to determine when a photo was taker	1. У
<u>US v Brady</u> (1979)²	microscopic hair analysis	У
<u>Lindsey v US</u> (1956) ³	effect of sodium pentothal	У
<u>Hawthorne v State</u> (1982) ⁴	battered wife syndrome	У
Sprynczynatyk v GM (1985) ⁵	hypnotically induced testimony	Ν
<u>US v Gould</u> (1984) ⁶	pathological gambling as a defense	e N
<u>Dowd v Calabrese</u> (1984) ⁷	polygraph	N

Polygraphs:

A polygraph uses body functions to determine whether someone is lying. It is based on the theory that one cannot lie without one's respiration, heart rate and pulse being effected. The readings are taken during questioning and measure and record heart rate, blood pressure, respiration and galvanic skin response⁸.

² 595 F2d 359 (6th cir)

¹ 659 F2d 750

³ 237 F2d 893 (9th cir)

⁴ 408 So2d 801 (Fla Dist Ct App)

⁵ 771 F2d 1112 (8th cir)

⁶ 741 F2d 45 (4th cir)

⁷ 595 F.Supp 430

⁸ the electricity given of by the skin is moist from sweating.

In an amicus curiae⁹ brief to the Supreme Court in another case, the Committee for Social Sciences stated that polygraph tests are generally accepted among psychologists and psychophysiologists. It would have no problem passing the evidentiary requirements in <u>Frye</u>.

The real problem with the polygraph test is in the low level of training of the technicians who perform the tests. The idea that "psychopaths" can beat the polygraph is ridiculous. Psychotics should not be given the test when they are having a psychotic episode but are otherwise able to take it.

⁹ a brief or argument filed by a person or organization other than the defense or plaintiff. Amicus Curiae is Latin and means "friend of the court."

QUESTIONS Frye v US

- 1. How much testing should be done before science is admitted into evidence?
- 2. What questions would you ask an expert witness to determine if he/she is an expert? List three.
- 3. Should experts be paid? Why or why not?
- 4. All science begins as "new" or experimental. How long should it take before it becomes "real" science?
- 5. Fingerprints are now considered good evidence after about 50 years. But, they are not as iron clad as we might think. Often partial fingerprints are left and are difficult to identify. But, the public likes fingerprints. Should public opinion have anything to do with admission in court? Why?
- 6. Today, lie detectors are not allowed in evidence. Why? Should they be?
- 7. In his book, <u>The Truth Machine</u>, James Halperin envisions a future with a machine that can determine lying with no error. What effect do you think this would have on courtrooms?
- 8. Recently, the Supreme Court has given judges more control in determining what science should be allowed to be presented in trials. List two good things about this. List two bad things about it.

<u>Moore v. Regents of California</u> 249 Cal.Rep. 494 [1988], Cal.Lex. 2858. (1990)

In 1976, John Moore entered the University of California Hospital in Los Angeles, California for treatment of hairy cell leukemia. Hairy cell leukemia is a rare type of leukemia characterized by cells with hair-like projections that invade the spleen causing it to enlarge to engulf these cells. It usually attacks young males. Removal of the spleen, or

, is the generally accepted initial treatment of hairy cell leukemia and it often produces long-lasting improvement of many months or even several years. Therefore, as treatment of his condition Moore's spleen was removed in October of 1976.

Moore's condition went into remission and he was thrilled with the cure. From November, 1976 through September, 1983 Moore returned to California from Washington state to have blood drawn and other bodily substances removed (serum, bone marrow and sperm). He was told these procedures were part of his treatment and all his expenses were paid by UCLA. On April 11, 1983 Moore was asked to sign a consent form which allowed the doctors to engage in research on his cells. Moore signed the form.

The doctors had determined that the cells of Moore's spleen were unique because they created a protein, called a lymphokine, that had been used for treatment of certain cancers. A cell line, using genetic engineering, created a continuous culture of his cells that would last forever. By joining sections of his spleen cell's DNA to the DNA of E. Coli and the resulting cell line produced a pharmaceutical product that had tremendous medical uses as well as a high commercial value.

On March 20, 1984 Moore's doctors were issued a patent for the cell lines by the U.S. Patent Office with Dr. David Golde and Shirley Quan listed as inventors. The cell line was originally named the "Moore Cell Line" but later changed to "RLC Cell Line". Doctors Golde and Quan made agreements with Sandoz Corporation and Genetics Institute, Inc. to commercially develop and investigate this cell line. For this, they received the option to buy 75,000 shares of Genetics Institute stock at a reduced price and \$330,000 cash.

A lawsuit was filed on September 9. 1984 that charged Golde, Quan, the Regents of the University of California, Sandoz and Genetics Institute, Inc. with the major cause of action called conversion, the removal of another's property. If an argument for conversion were to hold, Moore's attorneys had to prove that his cells and their products were his property.

RESULTS Moore v Regents of California

Trial Court:

The trial court did not allow the claim of conversion because Moore did not specifically state, when he had his surgery, that he did not want his tissue used for research, and, he failed to attach a copy of the release for the splenectomy to the court documents. They did not address the question of ownership of the cells, essentially forcing this decision to a higher court. John Moore appealed this ruling to the California Court of Appeals.

Appeals Court:

After a long discussion, the California Court of Appeals, on July 21, 1988, in a two-to-one decision, stated that Moore's allegation of a property right to his own tissues "is sufficient as a matter of law." Because the rights to the cell line had already been sold, it became only a matter of the court deciding who should share in the proceeds. The doctors appealed to the Supreme Court of California.

Supreme Court:

The Supreme Court of California on July 1, 1990 reversed the appellate courts decision that Moore owned his cells and sent the case back for a new trial on the grounds of breach of doctor/patient relationship, because Dr. Golde should have informed Moore of the possible future use of his cells.

In considering the issue of ownership, the court stated that if Moore was allowed the ownership interest in his cells this could impose "a duty on scientists to investigate the consensual pedigree of each human cell sample used in research." This, the court reasoned, was too difficult and confining. It might also increase litigation in these areas. The court was afraid that scientific experimentation, a very necessary thing, would become more difficult if they didn't allow doctors to work with human cells freely. The work with human cells is extremely important because testing the effects of drugs and other treatments on the living human cells must occur before we test them on human beings. If the scientists had to check into the ownership of the cells before they used them, it would take a great deal of time and be expensive. Scientific study would be slowed.

The court would not allow Moore to stop the companies from using his cells or have a part in the profits. But, the quality of the doctor's relationship with his patient was important. Although the court did not allow John Moore to recover any money by claiming ownership of the cells, they said he could go back to court and sue the doctors because they did not inform Moore that his cells were being used for this purpose.

There has been no suit filed on behalf of Moore, as suggested by the court. Therefore, it is assumed that a settlement was reached for an undisclosed amount, probably with a gag order.

Issues Moore v Regents of California

Informed Consent:

Moore's attorneys also claimed that Moore was not allowed informed consent. All patients who undergo surgery or any medical procedure must sign an informed consent form. The doctor is responsible for telling the patient all the information needed to make an informed consent. If the doctor does not tell the patient enough, or, he misrepresents what is to be done, he can be sued. In Moore's case, he did sign consent for the surgery, and, later, for the blood tests, but was not informed that his cells could be used and might be sold.

In other cases, doctors have done experimental work on prisoners and others without telling them how serious the consequences might be. In these cases, such as the Tuskeegee Institute case, there were serious results. In the Tuskeegee case, in the 1940s, men were injected with syphilis germs and then given experimental drugs to see if the syphilis could be cured. The problem was they were not told they had syphilis. When the experimental drugs did not work, the patients were sent home. Twenty years later, many died from the disease. Cases such as this paved the way for informed consent laws. As the years went by, these laws were refined and more and more information is now necessary to insure informed consent.

The Doctor/Patient Relationship:

Because of a lack of informed consent, Moore's attorneys argued that his relationship with his physicians was breached. Due to this breach, Moore was treated fraudulently and suffered from extreme emotional distress.

Conversion:

Conversion occurs when one's property is taken by another. In order to prove conversion, Moore's lawyers needed to prove that his spleen cells were his property. This argument was ultimately shot down by the California Supreme Court.

SCIENCE Moore v Regents of California

John Moore had a condition known as Hairy Cell Leukemia, a very rare condition. Leukemia is a condition where the white blood cells grow at a an advanced rate. In Hairy cell leukemia (HCL), specific white blood cells, mature lymphoid cells, proliferate. The cause of the illness is not known.

The name, hairy cell leukemia comes from the view of the cells under the microscope

Before 1984, with the invent of chemotherapy, a splenectomy (removal of the spleen) was the only treatment.

Cell lines are created by taking cells and continuing to proliferate them almost forever. A cell line, called HeLa, were cells taken from Harriet Lane, a woman who died of cervical cancer. This was almost 50 years ago. Today, medical students still study these cells in pathology to learn what cancer cells look like. In Moore's case, his cells created a special protein called a lymphokine. By cloning the gene for this protein and using recombinant DNA technology, the doctors created a cell line that made the lymphokine. This could then be placed in a bacterial cell and made in large quantities by the drug companies.

<u>Davis v Davis</u> 842 SW 2d 588 (Tennessee Ct of Appeals 1993)

In their marriage Junior and Mary Sue Davis, due to fertility problems, had gone to a infertility clinic and had a procedure called invitro fertilization. In this procedure, her eggs and his sperm were fertilized in the laboratory and 9 embryos were produced. Two were placed in Mary Sue's uterus and 7 were frozen. The two embryos that were implanted did not become a pregnancy. The Davis' were planning to come back and implant the other seven, but, they found the situation of the marriage unbearable and decided to divorce. Junior and Mary Sue asked the divorce court of Tennessee to make a judgment no other court had looked at before, each was asking for the embryos as part of the divorce settlement.

Junior wanted the embryos to destroy them, while, Mary Sue wanted to implant the embryos. She argued in defense of her right to proceed with the implantation, that the embryos were examples of potential human life, not typical property. But, if they were to be regarded as property, she should have a say in their disposition under the divorce laws in force in Tennessee. She also entered a counter-claim that Mr. Davis be ordered to pay child support in the event that she bore a child.

Junior's attorney argued that he should not be "forced" to be a parent, this was his right under the Constitution and that an "embryo" is not a person and, therefore, they could not be considered as children.

The court needed to decide if the embryos were property or children, or neither. If considered property, they would be split, as in most divorce law. If children, custody would have to be awarded.

The trial court, the first court, awarded custody of the embryos to Mary Sue, calling them "children in vitro" and directed that she be allowed to implant them. Then, Junior appealed the ruling to the Appellate court of Tennessee.

RESULTS <u>Davis v Davis</u>

Trial Court:

Their decision was to award "custody" stated that the wife be "permitted the opportunity to bring these children to term through implantation." They also decided that embryos were "instances of human life" and, therefore, had a right to life.

They used terminology that referred to the frozen embryos as "pre-embryos".

Appellate Court:

The court rejected the "right to life" rationale. Their decision was based on the fact that the trial court decision was inconsistent with Tennessee law allowing abortion. They also brought up the fact that Junior had a right NOT to be a father and awarded control of embryos to Junior and Mary Sue jointly. The court held that the Davis' shared an interest in the frozen embryos.

The Supreme Court of Tennesee:

They concluded that the frozen embryos are neither "persons" or "property" but "occupy a position of special respect because of their potential for human life." They felt that the main issue here is the individuals Constitutional right to privacy. If a person has a right to procreate, then they have a right NOT to procreate. If Mary Sue was allowed to implant the embryos, Junior would have no control over his parental status. Being an unwilling parent would place financial, emotional and legal burdens on Junior. Therefore, they awarded the embryos to Junior.

ISSUES Davis v Davis

In <u>Skinner v Oklahoma</u> (316 US 535 [1943]), the US Supreme Court recognized the right to procreate is one of a citizen's "basic civil rights". In <u>Roe v Wade</u> (see chapter eight), the court clearly held that an individual has a right to prevent procreation. In <u>Carey v Population Services</u> (431 US 678 [1977]), the Supreme Court stated "the decision whether to bear or beget a child is a constitutionally protected choice."

Therefore, the Appellate Court's ruling was not in accord with state and federal decisions, and the Supreme Court was clear. Giving the woman complete control over implantation is the same as a court deciding that men may be required to become a father against their will.

Three theories have arisen in regard to the status of embryos. First, is that life begins at conception. Obviously, if one hold this theory, the frozen embryos in <u>Davis</u> would be considered "children" and should be treated as such. Therefore, these embryos should be implanted and given a chance for life.

Second, the embryos are mere property. They should, therefore, be treated no differently than other human organs or tissues. This view holds that embryos should be transferred whenever possible but discarded embryos should be kept or used. In <u>York v Jones</u> (717 F Supp 421 [1989]) the Eastern District Court of Virginia demanded that an infertility clinic allow the Yorks to take their embryos with them when they moved to another state. The contract between the Yorks and the clinic continually referred to the embryos as the "property" of the Yorks.

Third is a theory in between the two listed above. This theory holds that the "pre-embryo" is more than human tissue but not an actual person. It is due greater respect than other human tissue yet not as a person. The Davis court held this view.

SCIENCE Davis v Davis

In Vitro Fertilization had a long history. The first "test tube baby", Louise Brown, was born in England in 1978. Couples with infertility problems are seeking out help and this seems to be one of the viable alternatives.

During the process, sperm and eggs (either from the couple or donors) are placed in a dish and watched by a lab technician until fertilization occurs. Then the embryo or embryos are incubated until they reach the 8 cell stage and then are implanted in the uterus of the woman.

Embryos that are not implanted are frozen, called cryopreservation, in liquid Nitrogen and can be kept for a number of years. Recently, a child was born from an embryo that had been frozen for 7 years.

QUESTIONS Davis v Davis

- 1. To whom should the court award the embryos? Why?
- 2. If neither were awarded the embryos, what should happen to them? Give both the pro and con.
- 3. Which attorney's argument do you agree with? Give three reasons why.
- 4. In Australia, two frozen embryos were left when a couple died in a plane crash. The couple had millions of dollars and many women wanted to be implanted with these embryos, who they thought would inherit the money. The Australian court decided no one would get the embryos. Do you agree with this decision? Why or why not?
- 5. Is there a duty to protect human embryos from harm? If so, who should protect them? If not, why not?
- 6. What should be done with unclaimed frozen embryos?
- 7.. What should be included in a contract for a couple going through IVF? List some possible choices.
- 8. After many tries to get pregnant, what could the Davis' have done besides IVF (research possible options)?

<u>Johnson v Calvert</u> (5 Cal 4th 84; 1993 Cal Lexis 2474 (1993)) 19 Cal Rptr 2d 494 (1993)

In January of 1990, Anna Johnson and Mark and Crispina Calvert entered into a surrogacy agreement. Anna would carry the Calvert's baby because Crispina had a hysterectomy 12 years previous due to of benign tumors. Her ovaries were still producing eggs.

The Calverts wanted to have their own genetic child and began looking into surrogacy and invitro fertilization. With this plan they would be able to have a child that resulted from the union of their sperm and eggs, and with the help of a surrogate, carry the child to term.

Crispina met Anna Johnson at the Western Medical Center where she worked. She was a 32 year old nurse with a five year old daughter who had previously had four miscarriages. But, during her interview with the Calverts, Anna did not reveal this medical history.

The contract that was signed would give Anna \$10,000 in installments over the length of the pregnancy as well as a \$200,000 life insurance policy. The baby would be created through invitro fertilization using the sperm of Mark and the egg of Crispina. Anna would deliver the baby and relinquish all parental rights which would go to the Calverts.

The implantation occurred on Jan. 19,1990 and a pregnancy was confirmed two weeks later. Then the problems began. Anna complained of numerous medical problems, changed doctors a number of times, asked for more money and quit her job. At this time she finally told the Calverts of her previous miscarriages. They were stunned.

After a phone call in which Anna asked Mark to drive her to the hospital and he refused, she began to think about keeping the baby. She filed a law suit asking to be declared the legal mother of the unborn child and the Calverts did the same.

A baby boy was born on September 19, 1990 and DNA tests showed the Calverts to be his biological parents. A hearing was held to determine the interim custody of the baby that ended in a stalemate and the judge was going to send the baby to a foster home. Anna agreed to allow the child to go home with the Calverts. She was granted three hour daily visits.

But, a trial was still to come.

RESULTS Johnson v Calvert

Trial Court:

On October 22, 1990 the court granted the Calvert's exclusive parental rights to the baby. Anna Johnson appealed.

Supreme Court of California:

The American Civil Liberties Union (ACLU) filed a brief with the court stating that the surrogacy contract was not valid because it gave away Anna's right to the child before birth (see issues).

The Supreme Court ruled:

- -genetic parents (the Calverts) are the natural parents because they intended to have and raise the child.
- -the surrogacy contract is good.
- -the surrogacy contract is not against public policy
- -the surrogacy contract does not deprive the surrogate (Anna Johnson) of her Constitutional rights.
- -that they could not decide this case on "the best interest of the child" because it would confuse concepts of custody and parentage.

ISSUES <u>Johnson v Calvert</u>

Contract law:

This case involved a contract between Anna Johnson and the Calverts. In this contract, Anna agreed to carry their baby and give it up to them at birth. The validity of this contract was one of the issues decided by the courts.

Contracts must take into consideration two things: One, the bargaining position o the parties involved and, two, what was the affect of the agreement on parties not part of the bargain.

Also a contract is considered invalid if it violates public policy. Public policy does not allow, by statute, selling a child or consent to adoption BEFORE birth.

Other Issues:

Who is the mother? The court stipulated very early in the trial that the father was Mark Calvert but the issue of the mother was important in the decision. Genetic testing had determined that the genetic mother was Crispina Calvert, but the court heard witnesses that said that the woman who carries a child to term bonds with them.

The court decided not on the genetic evidence but on the fact that Crispina "intended" and wanted to be the mother.

"The Best Interest of the Child": Courts are very concerned about what is best for the child. The court in <u>Johnson</u> decided that allowing Crispina to be the mother was in the child's best interest because a child's interest is "unlikely to run contrary to those of the adults who chose to bring the child into being."

SCIENCE <u>Johnson v Calvert</u>

An increase in infertility has brought about many new reproductive techniques (often called Artificial Reproductive Techniques or ART). One of these is invitro fertilization (IVF).

In IVF, a sperm and egg are placed in a petri dish and watched under a microscope until the sperm penetrates the egg. Then the dish is placed in an incubator. When the embryo is at approximately the 36 cell state it is placed in the uterus of a woman and carried for 9 months until birth.

IVF is often used when the sperm have a motility problem (cannot travel fast enough or in the right direction), when the fallopian tubes are blocked or removed (then the sperm and egg cannot fertilize each other naturally) and when a hysterectomy has been done and the ovaries, fallopian tubes and uterus have been removed.

Surrogacy can be combined with IVF. In surrogacy a woman either volunteers or contracts to carry a fetus for another couple and give birth to it. This ART is usually used when a patient has had their uterus removed (hysterectomy) as with Crispina Calvert, or cannot carry a baby to term due to miscarriage and other hormonal problems.

Surrogacy can be done in two ways. One, the surrogate is artificially inseminated (a doctor places the sperm inside her uterus with a syringe) with the sperm of the contracting father. In this case, the surrogate is the genetic parent of the child.

Two, the surrogate is implanted with an embryo formed by IVF. This embryo is the genetic child of the contracting father and mother. This was the case in <u>Johnson v Calvert</u>.

QUESTIONS Johnson v Calvert

- 1. What should the judge decide in this case?
- 2. What arguments would you give if you were the Calvert's attorney?
- 3. What arguments would you give if you were Anna's attorney?
- 4. What part should genetics play in the parental rights of a child?
- 5. Could the court decide the parental rights of an unborn fetus? Why or why not?
- 6. Anna obviously did not tell the Calverts the entire truth about her medical background. Should this cut her rights to the child? Why or why not?
- 7. In a similar case, in 1987, in New Jersey ($\underline{\text{In Re Baby M}}$), the surrogate tried to keep the baby and the court decided that surrogacy contracts were not legal. Should the judge in this case (in California) use $\underline{\text{Baby M}}$ to decide this case? (Hint: in $\underline{\text{Baby M}}$ the surrogate had no genetic relationship to the child).
- 8. The Calverts had money and a good home for the baby, while Anna obviously had problems in this area. Should the judge take this into consideration, who or why not?
- 9. Now that we have the science to allow this, and many other, new reproduction techniques, should we use them?
- 10. Soon there will be an artificial uterus developed where a baby can actually grow for 9 months in the laboratory. Do you think this will do away with surrogacy? Will couples really use this technology? Will this type of gestation harm the embryo?
- 11. In the Johnson trial, one expert testified that a gestating (pregnant) mother often bonds with the fetus she is carrying. What do you think of this statement?

Amgen, Inc. v Chugai Pharmaceutical Co. 927 F.2d 1200

Both Amgen, Inc. and Chugai Pharmaceuticals held patents involving the production and marketing of a naturally occurring hormone called erythropoietin, or EPO. Amgen, a company based in California had a patent for the DNA sequence (or gene) that made EPO.

Before a patent can be awarded an invention three conditions must exist: (1) novel, (2) not obvious and (3) useful. Usually, naturally occurring substances cannot be patented. therefore, EPO itself could not be patented but, each company patented a procedure. Genetics Institute (GI), a subgroup of Chugai Pharmaceuticals, a Japan-based company, owned a patent for purification of the chemical itself (Patent number 4,677,195) entitled "Method for the purification of Erythropoietin and Erythropoietin composition. Chugai was issued its patent on June 30, 1987. Four months later on October 27, 1987, Amgen was awarded Patent number 4,703,008 entitled "DNA sequences encoding Erythropoietin."

EPO, a hormone made in the kidneys, stimulates the production of red blood cells. It has been used to help anemics (people who have a low number of red blood cells) make red blood cells. Some forms of anemia are fatal and this drug had the potential to save lives. (see science)

Amgen was using the gene for EPO to create the hormone by recombinant DNA techniques. (see science) Using these techniques, the gene is placed within a bacteria and the bacteria then makes EPO. Large numbers of bacteria can create large amounts of EPO which can be marketed to doctors for treatment of anemia.

When Amgen was awarded its patent, it immediately filed suit against Chugai, claiming that the Chugai's patent infringed on their patent rights. At the same time, Chugai filed a counterclaim.

RESULTS <u>Amgen v Chugai</u>

The suit filed by Amgen was heard in the Federal Court of the United States Court of Appeals. This court ruled as follows:

- --parts of both Amgen and Chugai's patents were valid.
- --Amgen's claim to patent the purification process of the DNA sequence for EPO and the patent on the host cells for recombinant DNA techniques was valid.
- --that Amgen's patent did not cover the process of producing EPO and ONLY covered the intermediary products (the sequence of DNA and the host cells)
- --Chugai's claim to pure EPO and EPO compositions was not valid but it did not rule on the validity of the process of purification of EPO itself.

Chugai took the case to a higher court and they found for Amgen..

- --Chugai didn't have a description of the actual gene, that is necessary for a patent because they had never actually synthesized the gene.
- --Amgen was ruled the first inventor because they had actually cloned and identified the gene. Therefore, Amgen holds a valid patent on the gene and rDNA host cells that produce recombinant EPO (called rEPO). But, even though Chugai cannot create EPO in the United States without infringing on Amgen's patent it can create it overseas. Lawsuits are continuing in many countries around the world.

ISSUES <u>Amgen v Chugai</u>

PATENT LAW:

The patenting of DNA and its recombinant products is troublesome. Patent law prevents patenting naturally occurring substances and DNA and the proteins made by DNA fit into this category. This allowed a great deal of creativity on the part of patent attorneys and the courts that heard the early cases. In <u>Diamond v Chakrabarty</u> (477 US 303) the Supreme Court decided that once a gene was isolated and cloned it was no longer a "naturally occurring" substance, therefore, leaving the door open for many more patents.

The court held that the conception of the EPO gene by Chugai was defective because it contained no "description" of the actual gene. This, they claimed could not be done unless you actually have isolated the gene. They said:

"We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated."

If a gene is patented it will then be used to create a specific protein, as with EPO, the patent must contain a clear "description" of the gene and protein. The court said that it is impossible to have that description unless you first have the gene. Therefore, Amgen who had isolated and cloned the gene, owned not only the gene itself but the process by which the gene makes the protein. (see science section)

CASES SINCE AMGEN:

The Amgen decision has been upheld by many cases since. In <u>Fiers v</u> <u>Sugano</u> (984 F2d 1164), in 1993, the Federal Circuit Court decided between two inventors. One had a "written description" of the protein human fibroblast interferon-beta polypeptide and the other had cloned the gene after the patent with the written description was filed.

The court, upholding <u>Amgen</u>, found that a written description did not establish conception because "success was not assured until the gene was in fact isolated and its sequence known.

In another 1993 case, <u>In Re Bell</u> (991 F2d 781), the Federal Circuit Court said that knowing the sequence of a protein did not allow a company to own patents on the gene that makes that protein. Even though the amino acid sequence allowed the scientists to backtrack to the DNA code, it didn't automatically allow them to patent the gene unless they had isolated and cloned it.

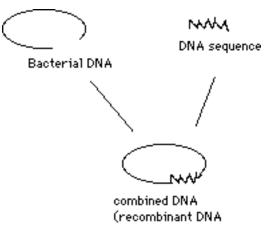
SCIENCE Amgen v Chugai

There are three parts to the process of creating a protein through recombinant DNA (rDNA) techniques.

First, the gene must be located, isolated and cloned. Cloning in this situation means duplicating the gene in the laboratory.

Second, the gene, now isolated must be placed in a host cell (usually bacterial cells) and then the host cell, using the DNA inserted, makes the protein as part of its naturally processes.

Third, the product (a protein) is produced and marketed. In the rDNA process the gene itself



is placed within the sequence of the bacterial DNA by using chemicals that cut and paste DNA at specific points in the sequence.

EPO has been used as a treatment for anemia. Anemia is a blood condition that results in a low red blood cell count. With seriously low red blood cell counts the correct amount of oxygen cannot be delivered to the body cells and serious problems can occur.

EPO controls the synthesis of red blood cells in the bone marrow and too little EPO causes serious anemia. EPO is made in the cells of the kidney by their DNA and goes to the bone marrow where it stimulates the production of red blood cells. The DNA in the kidney cells contain the gene that provides the code for production of EPO. Previously EPO was isolated

from the blood or urine of humans or animals but it cannot be concentrated in large enough amounts to be useful to anemics.

<u>Tarasoff v Regents of the University of California</u> 551 P2d 334 (Cal. 1976)

Dr. Lawrence Moore, a psychologist employed by the University of California hospitals, was treating Prosenjit Poddar as an outpatient. During a session in 1969, Poddar confided that he intended to kill his ex-girlfriend, Tatiana Tarasoff when she returned from her summer vacation.

Dr. Moore wasn't sure if he thought Poddar could actually kill Tatiana, but he wanted to be safe so he notified the campus police. The police detained Poddar but released him because he seemed rational and denied he was going to kill his ex. Poddar then stopped his treatment with Dr. Moore.

Three months later, Poddar killed Tatiana.

Tatiana's parents sued the University of California for malpractice claiming that the physician had a "duty to warn" Tatania and that it would have saved her life.

RESULTS <u>Tarasoff v Regents of University of California</u>

Trial Court:

The trial court found for the University of California (defendants) stating that no duty to warn exists, and, the plaintiffs (Tarasoff family) appealed.

Supreme Court of California:

Reversed, stating that therapists have a duty to take actions to protect third parties from violent patients, even if this breaches confidentiality.

They said that the therapist (Dr. Moore) cannot escape liability just because Tatania Tarasoff was not his patient, he still should have warned her. Also, when a therapist determines that his patient presents a serious danger to another, he or she has an obligation to use reasonable care to protect the intended victim from danger.

However, the doctor must have a special relationship with either the person who might cause harm or the potential victim before he can breach confidentiality. The potential victim must be identifiable and the harm must be foreseeable (see issues) and serious.

They stated: "Privilege ends where public peril begins."

Legislation

Some states have enacted legislation based on the <u>Tarasoff</u> decision. These laws require disclosure when certain dangers exist. They state that the therapist (or doctor) has an obligation to use reasonable care to protect a potential victim.

ISSUES <u>Tarasoff v Regents of University of California</u>

Foreseeability:

In all states, no duty exists for doctors to disclose medical information about their patients. As a matter of fact, most states consider such release of information criminal, and, considered confidential under statute.

But, under certain circumstances the <u>Tarasoff</u> decision allows physicians and therapists to release information about their patients to potentially victims.

The court in <u>Tarasoff</u> stated that "a defendant [therapist/doctor] owes a duty of care to all persons who are foreseeably endangered." In this case, foreseeability means that the doctor must be able to foresee that the victim both exists and may be harmed.

Relationship:

In addition, the doctor/therapist must have a "special relationship" with the person or patient. He has a "duty of care" that gives the patient/victim a right of protection.

This case has been applied to a number areas other than psychotherapy, making this case one of the most interesting ones.

- A. AIDS: In many cases all over the country, courts have recognized the fact that a person's HIV status makes them a danger to others, including spouses and other sexual partners. Tarasoff has been used to create a "duty to warn" partners of the HIV test results of patients because of the danger that is involved.
- B. Genetic Test Results: Most courts have not allowed the release of genetic information to families when the patient does not want the test results made public. Distinguishing these cases from Tarasoff, the patient's action (not to release information) does not harm others and the relatives are not being but put at risk due to the fact that already have the gene or not. However, one court stated that genetic information is a "family possession not a personal one" and allowed the litigation to

continue. (<u>Safer v Estate of Pack</u>, 677 A2d 1188 [1996]). So this is changing.

Some Cases:

Myers v Quesenberry (193 Cal Rept 773 [1993])

The doctor failed to tell a patient not to drive in an uncontrolled diabetic condition and she lost control of her car and struck a woman (the plaintiff). The court stated that "reasonable steps should have been taken to protect foreseeable victims from the patient's dangerous conduct." The doctor lost.

Reisner v Regents of University of California (37 Cal Rept 2d 518 [1995])

A doctor with an HIV positive patient (a woman) did not inform her, her parents, or her boyfriend of her status and the dangers of HIV transmission. The boyfriend became infected and sued the doctor stating that the doctor should have warned the girl and her parents and, then, he would not have been affected. The doctor argued that he didn't even know the boyfriend existed and, therefore, could not be responsible for protecting him.

The court said that the doctor had a duty to warn even though the parents and the doctor did not know that the boyfriend existed. They stated "once a doctor warns a patient of the risk to others and how the disease is spread he has fulfilled his duty."

Pate v Threkel (661 So 2d 278 [1995])

A daughter sued her mother's doctor because she contracted a form of thyroid cancer that is hereditary. She stated that if the doctor had informed her mother that the cancer was genetically transmitted, the daughter would have had checkups and would have detected the cancer earlier. The court said that the doctor should have known the hereditary aspects of the disease and warned the mother that her children were at risk. But, the doctor did not have a duty to warn the children themselves.

QUESTIONS <u>Tarasoff v Regents of University of California</u>

- 1. What should the court decide?
- 2. The Tarasoffs were asking for damages (money) to compensate them for the loss of their daughter. Do you think this is a good argument? Why or why not?
- 3. Did Dr. Moore do enough to protect Ms. Tarasoff?
- 4. If not, what more should he have done?
- 5. What could this mean for the future of medicine?
- 6. This case has been used in cases where a physician was questioning whether to tell a spouse that his/her partner has HIV. Do you think this is relevant?
- 7. If you were the attorney for the University of California what would you argue (list three things)?
- 8. If you were the attorney for the Tarasoffs, what would you argue (list three things)?
- 9. A woman and man are engaged, the woman has a genetic test and finds she is carrying the gene for cystic fibrosis, a recessive trait. Should the doctor tell the patient's fiancee? Why or why not?
- 10. How could Tarasoff be used in the argument in this case?

<u>Roe v Wade</u> 410 US 113 (1973)

Facts of Case One:

Texas had a law criminalizing abortion since 1854. Everyone knew about it. Jane Roe (a pseudonym) was a single woman living in Dallas County Texas. She was single and when she found out she was pregnant didn't know what to do. She was afraid of the back room, illegal abortions she had heard about. But, as far as she knew, the only way to get a safe, legal abortion performed by a doctor was if the life of the mother was at stake.

Facts of Case Two:

Doctor James Hallford, a licensed doctor in the state of Texas wanted the right to perform abortions. Many women had come to him hysterical and wanting to end their pregnancies. He had already been arrested for performing abortions under the Texas law. He claimed that the law was extremely vague and needed clarification. Sometimes, he said, he couldn't tell whether a woman's condition fell within the "life threatening" limit.

Facts of Case Three:

John and Mary Doe (pseudonyms) were a married couple with a problem. They had no children and Mary had a serious neurological condition. Doctors advised the couple not to get pregnant until such time that the condition improved. They were concerned that, should she become pregnant, there wouldn't be any way they could solve the problem. Her condition did not fall under the "life threatening" area, so she would not be allowed to have a legal abortion.

These three cases were all consolidated into one case, Roe v Wade, and heard before the Supreme Court of the United States on January 22, 1973.

RESULTS Roe v Wade

Trial Court:

The trial courts in all three cases found that none of the plaintiffs had a case to override the Texas abortion law.

District Court:

All three cases were consolidated into one and heard by the District Court (a three judge panel). The suits represented the situations of three residents of the state of Texas, a single pregnant woman, a doctor who thought the law was vague and was being criminally charged, and, a childless couple.

The district court held that:

- a. Jane Roe and Dr. Hallford had standing and could sue.
- b. The Does, however, could not sue because their situation was not controversial enough to file suit (probably because she was NOT pregnant).
- c. The Texas abortion statutes were void (not good) because they were vague and infringed on a plaintiff's 9th Amendment rights under the Constitution of the US.
- d. Even though the court felt that the abortion statutes were bad they denied an injunction allowing abortions because they felt that the ruling must come from a higher court.

The three plaintiffs appealed to the Supreme Court of the US. Supreme Court of the US:

The Supreme Court looked on these cases as one, but, ruled on all three areas--that of Roe, Hallford and the Does. They found the following:

- a. That Jane Roe had standing to sue, but the Court realized her pregnancy would have come to term before the process was complete--and it did. They felt that this did not make her case moot (not good).
- b. That Dr. Hallford's case should be sent back to state court because he had criminal charges pending against him. The court dismissed his case.

c. They dismissed the Doe's case.

This left only ROE.

The Supreme Court found:

The U. S. Constitution's "fundamental rights" clause was vague enough to include a woman's right to privacy and, therefore, her right to have an abortion.

This did not include her right to abort her fetus at any time and that some state regulation was possible concerning the timing of an abortion.

The Constitution does not define "person". This, and the fact that abortions were legal through a major part of the 19th century, led the court to determine that the word "person" as found in the 14th Amendment, did not include "the unborn".

The state (of TX) does have an important interest in protecting the life and health of pregnant women. A child cannot be protected by the state until it reaches viability (can exist outside the mother). The state, therefore, can regulate abortion after the point of viability but not before. (see issues)

The Texas law was not struck down completely by the Appellate court but the Supreme court said that it must fall. They stated that the law was unconstitutional and that the state authorities would realize this and strike down the law.

Personal results:

Jane Roe had a baby a year before this case was heard by the Supreme Court. She gave the baby up for adoption. Since then, she has become an anti-abortion activist and uses her pseudonym in speeches she makes all over the country.

ISSUES Roe v Wade

The state of Texas argued that it had a duty to protect prenatal life. This was based on the assumption that a human life is present from the moment of conception. Therefore the states right to protect all human life would extend to the developing fetus.

The plaintiff claimed that they were due the right of abortion because the Constitution gives everyone a right to privacy. Both courts noted that this is not a right specifically stated in the Constitution, which gives us "fundamental rights." But, previous cases have allowed this to extend to the right to privacy. They stated the fundamental right is "broad enough to encompass a woman's decision whether or not to terminate her pregnancy".

Viability Issue:

Viability, in medical and legal definitions, is when the fetus can live outside the mother's uterus. The court did not define exactly when that is, leaving such decisions to physicians and state legislators. The viability line, the point at which a baby can be born prematurely and still live, is changing all the time. With the invent of better prenatal care, intensive care units for premature babies and drugs to control the lung development, more and more babies are living after being born at 22 and 23 weeks of gestation. These medical advances are changing the issue.

Two important subsequent cases:

1. <u>Planned Parenthood v Robert P. Casey</u>, et al. (505 US 833).

This case challenges a Pennsylvania law that required that a woman about to receive an abortion give her informed consent and that she be provided with certain information.

The Supreme Court upheld <u>Roe</u> by stating that "the State...if it chooses may regulate...abortion." But, this is no way lowered the woman's right to decide.

2. <u>Doe, et. al. v Bolton, Attorney General of Georgia, et. al.</u> (410 US 179 [1973])

A group of doctors, nurses and social workers challenged the Constitutionality of the Georgia abortion law asking the court to declare the law unconstitutional.

A patient had applied to the "abortion committee" of an area hospital for an abortion and was turned down. She and the group were claiming that she had to relinquish "her right to decide when and how many children she will bear".

The court held that the provision that forced a woman apply to a committee and be approved by 2 physicians before an abortion could be granted was in violation of <u>Roe</u>.

Since Roe many states have tried to limit the rights given to women in 1973. Here are some examples:

- 35 states do not cover abortion with Medicaid funds.
- 16 states need parent consent for an abortion if the woman is under
 18.
- 32 states have mandatory reporting by doctors to health services.
- 24 states mandate that "reasonable steps to preserve life" be done.
- 50 states mandate that facilities that do abortions be licensed.
- · many states limit what funding can be used for abortions.
- 19 states have laws that do not allow use of fetal tissue for scientific research from abortuses.

Other states have tried to restrict abortions but have not succeed. Some that have been overruled by either state or federal courts are:

- notification of spouse.
- limit the right to get an injunction to allow abortions.
- · allow abortions only in hospitals.
- ban on saline injection (see science).
- · demand an ultrasound be done before abortion.
- · require residency in a specific area or state.

SCIENCE Roe v Wade

The medical procedure of abortion can be split into three areas (called trimesters).

First trimester: first three months

Second trimester: months 4-6
Third trimester: months 7-9

With each increasing trimester, abortions become more difficult.

In the first trimester, a suction method or pill induced method can be used. Little physical discomfort or difficulty occurs. The lining of the uterus is removed and along with it the fetus.

The second trimester is more difficult. Drugs or saline injection are used and the pregnant woman must go through a limited labor to expel the fetus. This is often done when prenatal testing shows an abnormality (chromosomal or genetic). This must be done in the doctor's office or hospital.

The third trimester is the most difficult. It is rarely done and can result in some physical harm to the mother. It involves a surgery or labor inducement and can be painful and long. A hospital stay is necessary and this procedure is usually only done in the most serious of circumstances (deformity of the child due to genetic conditions or life threatening to the mother). Only certain states allow this procedure.

<u>Mobley v. Georgia</u>

On February 17, 1991, John Collins was shot in the back of the head. This occurred during a robbery of the Domino Pizza Store in which he worked in Oakwood CA. On March 13, after being picked up for questioning, Stephen Mobley confessed to murder and armed robbery.

During this confession he boasted how John Collins fell on his knees and begged for mercy. Then he had himself tattooed with a Domino's logo and plastered his cell with Domino's boxes. His history included rape, robbery, assault and burglary. The prosecution said that "Mobley is evil, a cold blooded, heartless killer."

Daniel Summer, the court appointed attorney for Mobley, tried to get a plea of guilty entered and a deal for life in prison, but, the deal was rejected. The court was interested in the death penalty for Mobley. During questioning of Mobley's family, Summer met Joyce Ann Childers, his aunt. She told Summer that "volcanic, aggressive, physical abuse and violent behavior is prevalent throughout the family tree." Summer then remembered an article he had read in The Chicago Tribune in which scientists at Harvard, the NIH and overseas were conducting research on genetic ties to violence.

Before the sentencing hearing Summer contacted Dr. Xandra Breakefield, from Harvard Medical School, and Dr. Bahjat A. Farat at Emory University**. When Mobley's story was revealed the doctors began to see a pattern emerge of a family history of violence moving through a number of generations in Mobley's family. Both doctors offered their services free of charge, but Mobley would need specialized testing of urine and blood to determine if he suffers from genetic mutation of the gene for monoamine oxidase A, as the patients studied by Breakefield and Farat were.*

One might expect Mobley to come from poor family and bad surroundings, the opposite is actually true. Even though many of the people in Mobley's family tree were violent, many were amazingly successful. His father, for example, even though he refused to help Mobley's defense, is a self made millionaire. He tried sending his son to private school, then psychiatrists and finally, jail but stated, "He never developed a value system or a conscience." In the end he washed his hands of the responsibility.

The cost of the tests, about \$1000, was not available to Mobley and Summer asked the court to release funds for the test. This allowed the trial court, and eventually, the Supreme Court of Georgia, to weigh the question of validity of genetic causes of criminality.

*see mobley's family pedigree as PDF in CD file marked PEDIGREES

**see pedigree from Science article in file marked pedigrees

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