

**CALIFORNIA SCIENCE AND THE LAW CONFERENCE
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JUDICIAL ASPECTS OF BIOSCIENCE

INTRODUCTION

For two centuries, science has been a major force in people's lives. In the 19th century, it was chemistry. In the 20th century, physics literally exploded before our eyes. Traditionally, the hard and exact sciences like chemistry and physics have been the most highly regarded disciplines. However, in the 21st century, biology in general, and biogenetics in particular, will more than likely dominate advances in science. It is therefore critical to consider the legal and ethical consequences of bioscience, and its world-wide impact on the courts, the law, and society in the 21st century.

Only fifty years ago, Francis Crick and James Watson discovered DNA's double-helix structure. Now it seems that almost everyday, we hear about a new genetic breakthrough somewhere in the world. First, there was Dolly the sheep. Dolly was followed by "Suzie" the calf, "Dot Com" the piglet, "Cc" the kitten, "Promotea" the horse, and, in August 2005, "Snuppy" the dog. In 2003, scientists announced the birth of three genetically engineered miniature pig clones, a development hailed as a major step towards transplanting pig organs into humans.¹ Another group of scientists met in 2002 at the New York Academy of Sciences to discuss proposed experiments for using stem cells to create human-mouse hybrids.² In 2004, scientists in South Korea became the first to clone a human embryo, demonstrating the all-too-real potential to clone humans.³

With completion of the decade-long Human Genome Project, essentially all of the 3.1 billion biochemical "letters" of human DNA, the coded instructions for building and operating a fully functional human, have been deciphered.⁴ Armed with this genetic

code, scientists can begin teasing out the secrets of human health and disease at the molecular level, which at the very least will revolutionize the diagnosis and treatment of everything from Alzheimer's and heart disease to cancer.⁵ Scientists can also manipulate plants and animals to increase food production and combat environmental hazards.⁶ Modern genetic engineering eliminates the natural barrier between species that limits traditional cross-breeding techniques and enables us to shift desirable genetic traits between species that could never mate or produce viable offspring in nature.⁷ Thus, although modern genetic engineering is still in its infancy, its beneficial possibilities are unprecedented. It is no wonder, then, that each new genetic discovery is announced with tremendous excitement and anticipation.

Given the rapid pace of development, it is easy to be dazzled by the science itself, and to overlook the ethical and pragmatic considerations that are sure to follow. The legal and ethical issues, particularly for lawyers and judges, that have emerged in the wake of these astonishing advances are difficult and complex. Traditionally, the role of bioscience in American law was limited to matters of identity; DNA was used to establish paternity or compare blood samples. Today, however, the legal impact of bioscience extends well beyond the use of DNA evidence. Genetic testing is now used to help predict life expectancy or determine the likelihood of someone suffering from a certain disease. Scientists have developed, or are developing, over 900 genetic tests,⁸ which screen for diseases such as Tay-Sachs, Lou Gehrig's, Huntington's, and Gaucher diseases, cystic fibrosis, inherited breast and ovarian cancer, colon cancer, sickle cell anemia, muscular dystrophy, Li-Fraumeni syndrome, and various forms of Alzheimer's.⁹ And, sophisticated brain testing techniques are beginning to shed light on the truth of what people say, and the reasons for what they do.

Genetic and neurological tests will inevitably create tensions and raise new legal questions for society. On the one hand are the great benefits, such as more effective disease prevention, and treatment through early detection. On the other hand, advances in bioscience create enormous risks of privacy invasion, discrimination in employment and denial of health or life insurance. They also create the disturbing prospect of

classifying individuals by their DNA or their brain functioning. We must carefully consider, and balance, these risks and benefits, or litigation involving bioscience will certainly overwhelm us. As technology evolves and advances, science and law will become more deeply entwined. Technological strides have forced people to change and expand their ways of thinking about concepts such as privacy, discrimination, and life itself. To accommodate these changes, our legal system must be prepared.¹⁰

Unfortunately, in many ways, the legal system has already failed to keep pace.

This paper touches on only a few of the legal issues raised by advances in bioscience: DNA and brain testing evidence in court; privacy; discrimination in employment and insurance; issues in medicine and reproductive science and agricultural and environmental biotechnology. It identifies more questions and problems than answers and solutions. But that is its objective. Michael Oakeshott, the British philosopher and educator once said: “The pursuit of learning is not a race in which the competitors jockey for the best place, it is not even an argument or a symposium; it is a conversation.” Conversations about bioscience and bioethics are essential to obtaining a long-term perspective regarding their impact on our lives.

SCIENCE AND LAW

In many ways, science and the law are very different. Someone once said that the United States and England are two nations separated by a common language. We can say the same thing about science and law. Often, a single word has a different meaning in each discipline. For example, take the word “evidence.” In science, the word means “something less than proof.” Papers in scientific journals often begin with titles like “Evidence for” or “Evidence against” a particular theory. The authors of these scientific papers cannot prove their point, but they still present their results, which often have great value. Conversely, in law, if evidence does not help prove a lawyer’s point, it usually has little value. And, because of the rules of evidence, information that sometimes seems very important may not be heard at all.

Also, consider the word “error.” In law, and in common usage, the words “error” and “mistake” are synonymous. A legal decision can be overturned for judicial error. In

science, however, “error” and “mistake” have different meanings. During an experiment, anyone can make a mistake, and scientists have no obligation to report theirs in the scientific literature. They simply clean up the mess and try again. Error, on the other hand, is intrinsic to any measurement. Far from ignoring it, covering it up, or even attempting to eliminate it, scientists include a careful analysis of error in writing up their experiments to put limits on the certainty of their measured results.

Science and the law also differ in their objectives. The objective of law is justice. The objective of science is truth. The search for truth in science has no time limit. A court or a jury, on the other hand, must decide the case before it at the conclusion of the evidence. As the United States Supreme Court noted when setting the standard for admitting scientific evidence in federal court, “there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.”¹¹ Thus, a legal formulation or holding may reflect scientific advances only briefly before further advances render it obsolete.

Despite these differences, at their deepest level, science and the law share the same aspirations and many of the same methods. Using structured debate and empirical evidence, both disciplines seek to arrive at rational conclusions that transcend the prejudices and self-interests of individuals.

DNA EVIDENCE IN COURT

Of course, bioscience has already played an important role in our courtrooms for some time. Genetic testing has revolutionized criminal investigations and reinvented the field of forensic science. DNA has had a dramatic effect on questions of identity in criminal cases. Police, prosecutors and defense counsel rely heavily on DNA evidence to do their jobs. The federal government and every U.S. state are busily compiling DNA databanks to store the genetic information of felons so that they can later be tested against samples from crime scenes. Databanks for sex offenders have existed for years. Using these databases, law enforcement authorities have been able to make arrests in crimes that have gone unsolved literally for decades. For example, as of June 2005, the

FBI's national DNA database, which includes genetic profiles of over 1.4 million offenders, produced over 23,500 DNA matches assisting in more than 25,400 investigations.¹² In 2004, the United States Congress appropriated \$755 million dollars to expand the national database, to fund testing of up to 300,000 unprocessed samples, to improve technology, and to test prisoners who continue to assert their innocence. At the same time, it authorized the FBI to include in its national database all DNA samples collected by states.¹³ As the breadth of the databases grows, so does the potential for expedited investigations and accurate identifications. Currently, at least eight bills are pending in the U.S. Congress regarding DNA databases.¹⁴

Today, the impact of DNA evidence in criminal trials is not confined simply to matters of identity. In a recent death penalty case in Georgia, a defendant complained that his counsel conducted an inadequate mitigation defense by failing to pursue genetic testing that might have shown a genetic basis for his violent and antisocial behavior.¹⁵ The highest state court in Georgia affirmed the death sentence, but not because it questioned this use of genetics as mitigation evidence.¹⁶

This Georgia case points in a new direction for genetic testing in criminal cases. Increasingly, defendants seek to use their own DNA to deny scienter responsibility for their unlawful actions. They hope to prove they have a genetic pre-disposition to violence or other anti-social behavior, and therefore, are not culpable for their offenses. According to these defendants, they did not act voluntarily, but acted instead as the result of their genetic makeup, something over which they have no control. This argument has found some support in our courts. In one case, an accused murderer was found not guilty when her violence was linked to her Huntington's disease.¹⁷ In California, two alcoholic lawyers were convicted in separate matters for embezzling money from their clients. The attorney who claimed that a genetic disorder caused his alcoholism received a lighter sentence.¹⁸

The theory that violent behavior may be beyond a defendant's control because of his or her genetics raises important philosophical questions about culpability and free will. Strategically, it may end up hurting a defendant's case more than it helps. As the

Illinois Supreme Court has observed, evidence that a defendant's family has a history of violence is not necessarily "mitigating"; though it may "invoke[] compassion," it may also demonstrate the defendant's "potential for future dangerousness."¹⁹

Of course, we are also likely to see more uses of genetic evidence in civil trials. Defendants in personal injury cases may look to genetic information to limit their liability. For example, when a chemical company was sued on behalf of a child allegedly injured by the company's toxins, the chemical company persuaded a judge to order genetic testing on the child to prove that his problem was genetic and not due to exposure.²⁰ Similarly, where a plaintiff seeks to recover damages for a life-long disability, a defendant may try to limit liability by showing, through genetics, that the plaintiff may die earlier than expected. In the future, tobacco companies may also try to avoid liability by showing that a plaintiff's cancer was due to "genetic susceptibilities."²¹

Family court judges also must deal with the impact of genetic evidence. Traditionally, genetic tests have been used to determine paternity. Today, family court judges are also using them to determine questions about parental rights. In South Carolina, a judge deciding whether to terminate parental rights ordered a mother to be genetically tested for Huntington's disease.²² Obviously, the next step would be for a court, in a contested custody case, to order genetic testing to determine which parent is more likely to live longer or suffer from anti-social disorders.

As genetic technology becomes more commonplace, we will see other novel questions regarding use of this information in the courtroom. For example, what do we do with a request to exhume a body in order to establish inheritance rights? One New York court denied such a request.²³ But an Ohio court granted one, stating: "[W]e are entering into a new area. Science has developed a means to irrefutably prove the identity of an illegitimate child's father. No longer are we dependent upon fallible testimony The accuracy and infallibility of the DNA test are nothing short of remarkable. We live in a modern and scientific society, and the law must keep pace with these developments."²⁴

BRAIN EVIDENCE IN COURT

Similar legal, moral and philosophical issues are arising, and will continue to arise, from advances in neuroscience. In July 1990, at the request of the United States Congress, the first President Bush proclaimed the nineties, “the Decade of the Brain,” and called for “appropriate programs” to implement his proclamation.²⁵ By some accounts, our knowledge of the brain doubled during that decade.²⁶

One of the main advances in this area has been the development of sophisticated brain scanning technology, which lets us see “what the brain is doing while it does it.”²⁷ This technology, which is called functional imaging, shows changes in the brain’s blood flow during some behavior, thought, or activity; which in turn shows which parts of the brain are active during that behavior, thought, or activity.²⁸

Many believe that functional imaging technology will someday have a tremendous impact on law and law enforcement. In 2001, researchers reported that “[t]elling a lie produces telltale changes in the brain” that can be detected with functional imaging technology.²⁹ Brain scans of research volunteers show increased activity in particular areas of the brain during periods of lying.³⁰ Ultimately, then, we may be able to use imaging technology as the ultimate lie detector. Other research indicates that using brain imaging technology, we can detect bias and distinguish false memories from true memories.³¹ Of course, this information would be very useful both in dealing with witnesses and in picking juries.

Significant technical obstacles remain to be worked out before imaging technology can be effectively used in any of these ways. But even if the technical obstacles are overcome, several legal issues will remain. For example, how will this technology affect the role of the jury? Determining the credibility of witnesses has traditionally been treated as one of the jury’s “core function[s].”³² Should we allow this function to be taken over—either formally, or in fact, because of the great weight jurors often give scientific evidence—by this kind of

brain imaging evidence? May a witness, a suspect, or even a prospective juror be compelled to submit to a brain scan? This question itself implicates several additional issues, including: privacy, because a brain scan taken for one purpose may reveal additional and very personal information; and safety, because imaging studies involve at least some degree of risk.³³

But while brain-scan-based lie detectors may be a thing of the future, the use of brain imaging technology in the courtroom is already here. In general, imaging studies show that if you put someone in a situation that might produce fear or hatred, the part of the brain that responds is not the part we use for rational decisionmaking.³⁴ And, in any particular case, an imaging study can show whether the parts of someone's brain responsible for impulse control, empathy, aggression and violence are either overactive or underactive.³⁵ It is not surprising, then, that in a number of criminal cases, defendants have offered brain scans to show that they couldn't have formed the mental state necessary for conviction, or to support an insanity defense, or to argue for a reduced punishment. Some of these claims have succeeded; others have failed, either because the evidence was kept from the jury by the court or simply was not believed.³⁶ Some defendants have successfully obtained new trials based on a court's refusal to authorize neurological testing or to admit brain imaging evidence.³⁷ As these cases show, brain imaging evidence, like genetic evidence, implicates philosophical concepts of culpability, individual responsibility, and free will that currently lie at the heart of our criminal law. "Should offenders be absolved of criminal responsibility, on the grounds that their neural makeup makes them bound to offend?"³⁸ On the other side of the coin, should prosecutors be allowed to introduce brain scans, either during trial to show that the defendant committed the crime, or during sentencing to show the defendant's future dangerousness? Should parole board's consider this evidence in deciding whether to grant parole? Should law enforcement use brain scans to identify potential offenders—and preemptively detain them?

Brain imaging technology has already played at least some role in a landmark U.S. Supreme Court decision. In a very high profile, 5 to 4 decision in 2005, a majority of the court relied partly on brain scan evidence in holding that the Constitution prohibits states from executing offenders who are under 18 when they commit capital crimes.³⁹ Several medical organizations participated in the case through what is known as a friend-of-the-court brief. In that brief, they detailed brain imaging studies of adolescents showing that the regions of the brain associated with impulse control, regulation of emotions, risk assessment, and moral reasoning, do not fully mature until after the age of 18.⁴⁰ In holding that executing juveniles is unconstitutional, the majority of the court noted that these “scientific . . . studies . . . tend to confirm” what “any parent knows”: that “ ‘a lack of maturity and an underdeveloped sense of responsibility are found in youth more often than in adults,’ ” “ ‘are more understandable among the young,’ ” and “ ‘often result in impetuous and ill-considered actions and decisions.’ ”⁴¹

Brain scans have also proven useful in terms of another subject that often comes up in criminal law: addiction. Research in neuroscience has enabled us to make much progress “in understanding the biological basis for addiction,” which was one of the “major target[s] for the Decade of the Brain.”⁴² Based on imaging studies that show us what is happening in the brain of someone who is going through withdrawal,⁴³ neuroscientists have found that “the brains of addicts are different from those of nonaddicts.”⁴⁴ They have also found that abused substances “stimulate the brain’s reward system and induce feelings of pleasure that can override the basic survival activities.”⁴⁵ The hope is that we can use this information to develop pharmaceuticals to effectively treat addiction, which would help us deal with the so-far intractable drug problem that inundates our courts.⁴⁶

Another brain-based technique that has gotten a lot of publicity recently is known as “brain fingerprinting.” According to its proponents, brain fingerprinting tells us whether certain information is present or absent in a person’s memory.⁴⁷ The technique is based on the principle that when a person recognizes an object or

idea, his or her brain will emit an electrical response that is involuntary, distinctive, and measurable using electroencephalogram (EEG) sensors.⁴⁸ In theory, by exposing criminal suspects and defendants to crime-related information and measuring their brain responses, we can determine whether they know details of a crime that only the perpetrator could know, or whether they have memories consistent with their alibi.⁴⁹ In November 2001, Time Magazine profiled the inventor of brain fingerprinting as one of the 100 innovators who may be “the Picassos or Einsteins of the 21st Century.”⁵⁰

There are, however, doubters who say that brain fingerprinting is not ready for forensic use.⁵¹ Some argue that “the procedure is too subjective.”⁵² Others claim we cannot determine “how the measured information [got] into [the] person’s brain as a memory.”⁵³ According to one researcher, who “replicated [the] procedure in the lab” using a Homeland Security grant, brain fingerprinting “only detected 50 percent of the criminals.”⁵⁴

Courts are already grappling with this debate. In 2000, Terry Harrington, who was serving a life sentence in Iowa for murder, asked for a new trial based on a brain fingerprinting test done more than 20 years after his conviction.⁵⁵ He claimed the test results showed that his brain did not contain significant information he would have known had he been at the crime scene, and *did* contain information consistent with the alibi he presented at his trial. After hearing from three expert witnesses, the trial court found that at least part of the science involved in the test was well established in the scientific community.⁵⁶ However, the court found that other parts of the test were not well accepted and were subjective.⁵⁷ It also expressed a more specific concern about the way the test was administered to Harrington.⁵⁸ Without really making a definitive ruling on the admissibility of the brain fingerprinting technique, the court denied Harrington’s request for a new trial.⁵⁹ In 2003, the Iowa Supreme Court reversed and granted Harrington a new trial, but it based its decision on other issues and expressly declined to consider the brain fingerprinting test.⁶⁰

In 2005, brain fingerprinting was at the center of another post-conviction appeal, this time in a death penalty case. Jimmie Ray Slaughter, who was on death row for murder, asked an Oklahoma court for a new trial based on a brain fingerprint test showing that his brain did not contain significant information about the crime.⁶¹ He submitted an affidavit from the test's inventor claiming that brain fingerprinting has been extensively tested and peer-reviewed, uses objective standards, has a very low error rate, and is generally accepted in the relevant scientific community.⁶² The court denied his request, finding that without corroboration, the inventor's claims, though "interesting," even "startling," were ultimately "unconvincing" and "legally insufficient."⁶³ In March 2005, with his legal options exhausted, Slaughter was executed.⁶⁴

Although the courts have so far given brain fingerprinting only a lukewarm reception, law enforcement has embraced it enthusiastically. In 1999, a Missouri sheriff asked the inventor of brain fingerprinting to test J. B. Grinder, who had been a suspect in an unsolved murder case for 15 years.⁶⁵ The test results showed that the record stored in Grinder's brain matched critical details of the crime scene that only the perpetrator would have known.⁶⁶ When presented with these results, Grinder pled guilty in exchange for a life sentence without the possibility parole. He later confessed to having committed three other previously unsolved murders.⁶⁷

Of course, the usefulness of these brain-based technologies in the courtroom is not limited to criminal law. Those involved in civil suits also want to know whether witnesses and possibly even prospective jurors are lying or biased. It is easy to imagine that a plaintiff alleging discrimination, or a defendant in a personal injury case trying to prove that the plaintiff is just faking pain, would be very interested in this kind of information.⁶⁸ The uses to which new scientific technology can be put may ultimately be limited only by a lawyer's imagination.

ADMISSIBILITY

Of course, each technological innovation and each novel attempt to use scientific evidence in court will present a new and difficult challenge for the judge

who has to decide whether to admit the evidence. In federal court and in states that follow the federal rules, before admitting evidence based on a new scientific technique, a judge must make “a preliminary assessment of whether the reasoning or methodology underlying the [technique] is scientifically valid.”⁶⁹ Needless to say, a law school education, although a valuable asset, does not do much to help a judge decide questions of scientific validity. To put it more bluntly, as the California Supreme Court recently did, most judges are “ill suited to make such determinations.”⁷⁰ California has a different rule; rather than decide whether a new scientific technique “is scientifically reliable or valid,” California judges must decide whether the technique “is generally accepted in the relevant scientific community.”⁷¹ And, once a California appellate court publishes a decision finding a particular technique to be generally accepted, further challenges to the technique’s use may not be brought without “ ‘new evidence . . . reflecting a change in the attitude of the scientific community.’ ”⁷² Whichever test applies, new technology will surely put judges to the test.

PRIVACY

The legal implications of bioscience extend well beyond evidentiary questions in the courtroom. Privacy is one area of major concern and potential litigation. As James Watson once remarked: “We used to think our fate was in our stars. Now we know, in large measure, our fate is in our genes.”⁷³ DNA is the blueprint of life. For this very reason, genetic information is uniquely private and personal. A DNA test can reveal an immense amount of personal information. Your DNA contains information not just about you, but about all of your close blood relatives. Yet, it is extremely accessible. DNA samples can be obtained with relative ease from a wide variety of sources. Similarly, brain imaging technology may provide access to what many consider the most personal of all information: our very thoughts. As one criminal law professor recently put it, this technology “will put tremendous pressure on the [courts’] understanding of privacy. . . . ‘It’s not that they’re invading [your] space or [your]

car. It's that they're invading [you].”⁷⁴ Thus, as genetic and neurological information becomes more accessible and available, new privacy issues will inevitably follow.

In 2001, the United States Supreme Court identified one of these issues: what are the legal “limits” on the “power of technology to shrink the realm of . . . privacy” guaranteed under the Constitution.⁷⁵ Answering this question in today’s increasingly dangerous world puts our constitutional principles to the ultimate challenge. As Judge Alex Kozinski recently wrote: “New technologies test the judicial conscience. On the one hand, they hold out the promise of more effective law enforcement, and the hope that we will be delivered from the scourge of crime. On the other hand, they often achieve these ends by intruding, in ways never before imaginable, into the realms protected by the Fourth Amendment.”⁷⁶

Judges have already been facing this test of conscience in lawsuits by convicted criminals alleging that mandatory collection of blood samples for DNA profiling violates their 4th Amendment right of privacy. Virtually all of these challenges have been rejected, but not without controversy. When 11 judges of the Ninth Circuit Court of Appeals recently faced the issue, they were unable to produce a majority opinion.⁷⁷ Six judges voted to uphold the federal government’s DNA testing program, but the judge who provided the swing vote wrote a separate opinion using a different analysis and limiting his conclusion to convicted criminals who are still on supervised release.⁷⁸ As to those who have completed all aspects of their sentence, he posed this question: “Should the [DNA profile] be erased” because of the “substantial privacy interest at stake.”⁷⁹ Maintaining these profiles threatens our interest in privacy because, in today’s technologically-advanced world, “databases can be ‘mined’ in a millisecond using super-fast computers,” “extensive information can, or potentially could, be gleaned from DNA,” and “this data can easily be stored and shared by governments and private parties worldwide.”⁸⁰ Four of the dissenting judges sounded this similar warning: “[T]he DNA placed in the [federal] database contains sensitive information, and no one can say today what future uses will be made of it once it is entered into government

files.”⁸¹ “Even governments with benign intentions have proven unable to regulate or use wisely vast stores of information they collect regarding their citizens.”⁸²

Similar issues have come up in other contexts. For example, the men and women of the United States military are currently required to give blood and tissue samples to the Department of Defense for its DNA Registry, which helps identify those who are killed in combat. In 1995, two Marines refused to submit DNA to the Registry, because of concern that their genetic information might be used against them in the future. They also argued that the nonconsensual storage and use of their DNA violated their Fourth Amendment rights under the United States Constitution. They were court-martialed for their stand. A federal district court upheld the DNA sample requirement.⁸³

At least one federal court has upheld a person’s right to genetic privacy, if only to a limited degree. In 1998, the Ninth Circuit Court of Appeals held that an employer may not test employees for “highly sensitive” medical and genetic information without their consent.⁸⁴ The case involved an employer’s alleged testing of employees for syphilis, the sickle cell trait, and pregnancy, without their knowledge. According to the unanimous Ninth Circuit panel, “One can think of few subject areas more personal and more likely to implicate privacy interests than that of one’s health or genetic makeup.”⁸⁵

State legislators are also working to defend the genetic privacy interests of the citizens they represent. As of June 2005, five states defined genetic information as personal property, sixteen statutorily prohibited genetic testing or obtaining a person’s genetic information without the person’s informed consent, and 26 required a person’s informed consent before allowing disclosure of genetic information. However, most of these statutes contain exceptions that allow scientists to test a person’s DNA in research projects without obtaining consent.⁸⁶

Privacy issues relating to brain scanning technology have not yet reached the courts or the legislatures, but it is only a matter of time. Someday, we can expect that a court will have to decide whether it is constitutional to take routine brain scans of airplane passengers as they pass through airport screening equipment.

DISCRIMINATION IN EMPLOYMENT AND INSURANCE

Privacy problems also arise in employment discrimination. A recent University of Illinois survey of 84 Fortune 500 companies revealed that 35 percent used medical records, including genetic information, to make decisions about hiring, firing, and promotion.⁸⁷ A similar 1996 survey documented more than 200 instances of workplace discrimination based on the detection of genetic predispositions.⁸⁸ For example, in one case, a young social worker who received excellent performance reviews for several months was fired after her employer learned she was at risk for Huntington's Disease, a hereditary nerve disorder.⁸⁹ In another case, a 53-year-old man explained during a job interview that he had a genetic disorder, but that it had not yet caused any symptoms. At his next interview, he was offered the job, but was told that because of his genetic condition the offer did not include health insurance. He said he would accept these terms, but was later told that the employment offer had been withdrawn completely, again, because of his condition.⁹⁰

At least 31 states prohibit employment discrimination based on the results of genetics tests, and 24 states prohibit employers from requiring that their employees be tested.⁹¹ However, these laws vary widely in coverage, with some of the earlier ones protecting only individuals with specific genetic characteristics or particular genetic disorders.⁹² Some federal protection also exists. The Americans with Disabilities Act (ADA) provides protection against job discrimination for people who carry genes that predispose them to developing disease later in life. The compliance manual of the Equal Employment Opportunity Commission (EEOC) states that under the ADA, an employer may not discriminate against a person based on genetic information relating to illness, disease or other disorders. For example, an employer may not refuse to hire someone solely because he has a genetic predisposition to colon cancer.

In February 2000, former President Clinton signed an Executive Order prohibiting the U.S. Government from using genetic information when making hiring, firing, or promotion decisions. In February 2005, the United States Senate unanimously approved the Genetic Information Nondiscrimination Act of 2005. This act would

prohibit employers from discriminating on the basis of genetic information and would strictly limit an employer's ability to request genetic information.⁹³ An identical bill was introduced in the House, but is stalled in committee.

Hiring, firing, and promotion are not the only areas in which employers may seek to use their employee's genetic information. In 2001, the EEOC sued an employer for genetically testing its employees to determine their predisposition to carpal tunnel syndrome. The employer apparently hoped to limit its worker's compensation liability.⁹⁴ The case settled and the employer agreed to halt the testing. Ironically, the employer also agreed to serve as an advocate in favor of federal legislation prohibiting genetic discrimination.⁹⁵

Insurance coverage is another major area of concern. As mentioned earlier, scientists soon will have a battery of over 900 genetic tests. However, very few of the genetically detectable diseases or disorders can be treated successfully. Thus, insurance companies have a tremendous incentive to consider an applicant's genetic information. Some insurance companies require genetic testing as a condition of coverage. Others may increase premiums or deny coverage based on the test results. Studies have shown that 25 percent of people in families with a known genetic condition have been denied health insurance coverage because of their genetic status, whether they were sick or not.⁹⁶ For example, in one case, a life insurance company denied coverage for two children because one of them had Hurler Syndrome, a fatal genetic condition; it offered no reason for refusing to cover the child without the condition.⁹⁷ In 1996, researchers from Georgetown University in Washington, D.C., surveyed 332 people who either had genetic disorders or had family members with genetic disorders. Forty-three percent were denied health insurance, life insurance, or employment based on disclosure of this information.⁹⁸ With the rapid progress in genetic technology in just the past nine years, a new survey would surely show an even higher percentage.

President Bush has called for federal legislation banning the use of genetic information in health insurance,⁹⁹ and several such laws have been proposed in the United States Congress.¹⁰⁰ The Genetic Information Nondiscrimination Act of 2005,

which was unanimously approved in the Senate but is still pending in the House of Representatives, seeks to prohibit discrimination in health insurance. It would bar insurance companies from basing enrollment decisions or premium adjustments on genetic information, and from requiring an individual or a family member to undergo genetic testing.¹⁰¹ The Health Insurance Portability and Accountability Act provides some protection, by prohibiting group health plans from establishing eligibility requirements based on genetic information. However, the law does not cover individual plans.

At the state level, 43 states prohibit genetic discrimination by insurance companies.¹⁰² However, scholars question the effectiveness of these laws, arguing that they are either “seriously narrow or overly general and unworkable.”¹⁰³ Often, these state laws only prohibit discrimination based upon DNA tests or have other gaping loopholes. Because the results of genetic tests are often intermingled with other medical information, the line between what constitutes “genetic” information and what does not is razor thin.¹⁰⁴ Thus, insurance companies may still lawfully engage in genetic discrimination by testing gene products, such as proteins, or by researching family history.

All of the same issues may eventually come up with brain scanning technology. It is easy to imagine that in the future, employers, insurance companies, and even universities will require applicants to take brain scans.¹⁰⁵ As some have observed, “[t]he potential to pigeonhole, to discriminate, and to judge on the basis of [brain scan] test results could result in substantial negative consequences, including the development of a ‘neuroscientific underclass’ denied access to education and other social benefits on the basis of their neuroscience results.”¹⁰⁶

MEDICAL ISSUES

On the medical front, advances in bioscience unquestionably offer enormous benefits.

For the last 15 years, scientists and researchers have been trying to develop gene therapy techniques to treat a host of diseases and conditions. We now know that many diseases and abnormalities occur because a particular gene either does not work properly or is completely missing, and we end up with either too much or too little of certain proteins or enzymes. The idea in gene therapy is not simply to treat the symptoms of the disease, but to fix the problem at its core by inserting a healthy gene into a person's cells. To insert a healthy gene into a patient, researchers generally use a virus that has been altered so that it cannot reproduce or cause disease. The virus carries the healthy gene to the targeted cell and unloads it. Once inside the cell, the healthy gene can begin to function so that the body produces the right amount of the necessary enzymes and proteins. Despite slow progress and numerous setbacks, many scientists still view gene therapy as a medical revolution that will eventually offer a cure—not just a treatment—for a broad range of ailments, including cancer and AIDS.¹⁰⁷

Two other areas of global importance are cloning and stem cell research. In reproductive cloning, a cloned fetus is produced by implanting a cloned embryo into a woman's uterus. In therapeutic cloning and embryonic stem cell research, different types of tissues are grown from genetic material.¹⁰⁸ Embryonic stem cells are cells “whose job in the body is not yet determined.”¹⁰⁹ They are the precursors to all adult cells in the body, including the cells that make up our organs, like the liver and the pancreas. Because they have the ability to differentiate themselves, they are “good candidates for restoring tissues that have been damaged by injury or disease.”¹¹⁰ Therefore, the “goal of any stem cell therapy is to repair a damaged tissue that can't heal itself.”¹¹¹ For example, researchers have successfully demonstrated that “human bone marrow-derived adult stem cells can be coaxed to differentiate into airway epithelial cells,” which can be genetically altered potentially to treat cystic fibrosis.¹¹² Stem cell research advocates believe that these cells have the potential to treat a wide range of ailments and degenerative diseases, like Parkinson's disease or spinal cord injuries.¹¹³ Research in this area has taken off since 1998, when scientists first isolated human embryonic stem cells.¹¹⁴ In May 2005, scientists in South Korea announced what was hailed as a breakthrough in stem cell

research: the creation of the first “patient specific” embryonic stem cells. Using a patient’s ordinary skin cells, the scientists created stem cells that genetically matched the patient’s DNA.¹¹⁵

In addition, since 2003, when researchers finished decoding our DNA, the search for better, faster, and more effective medications has begun in earnest.¹¹⁶ Increasingly, scientists armed with our genetic blueprint can identify the individual molecules that make us susceptible to a particular disease.¹¹⁷ With this information, and some high-speed silicon-age machinery, they can build new molecules that home in on their targets like well-aimed arrows.¹¹⁸ In the new era of genomic medicine, doctors will treat diseases like cancer and diabetes before symptoms even begin and will use medications that, with exquisite precision, boost or counteract the effects of individual proteins by attacking diseased cells while leaving healthy ones alone.¹¹⁹ And, thanks to the emerging field of pharmacogenetics, patient-specific drugs will play a greater, and safer, role in our health care. Currently, medications that are *properly* prescribed make millions of people seriously ill and kill over 100,000 people each year.¹²⁰ But the era of “one size fits all” medication is ending, as physicians are learning to read a patient’s unique genetic code and tailor treatments accordingly. Researchers are now looking for the sites in the genetic sequence that differentiate one person from the next, which are called SNPs.¹²¹ Decoding the estimated 10 million SNPs and determining how they affect individuals could lead to the design of drugs matching particular DNA profiles, which would enable us to avoid the complications and side-effects of many traditional medicines and to attack illness at its core—the molecular level. Already, researchers have identified the most prevalent cell receptors for certain cancers and are developing antibodies to block the normal, destructive activities of those cells.¹²² Drug companies are searching for new ways to use existing drugs based on genomic studies. Treatments for AIDS, heart disease, depression, and even obesity may someday be available through pharmacogenetic research.

Again, these advances pose new ethical and legal challenges. Several have already arisen in connection with gene therapy research. In 1999, Jesse Gelsinger, an

18-year-old volunteer for a university's gene therapy study, who was in relatively good health at the time despite a metabolic condition, died from a reaction to a gene therapy treatment only four days after receiving it. Investigations into Gelsinger's death revealed some troubling information: the university failed to exclude him from the study as it should have based on his ammonia levels at the time of the treatment; it failed to mention, as part of the informed consent process, that monkeys given a similar treatment had died; and it failed immediately to report that two patients had experienced serious side effects from the gene therapy. More broadly, the investigations revealed that gene therapy researchers in general were substantially underreporting adverse events associated with gene therapy trials, that some scientists were asking that problems not be made public, and that there may have been at least six unreported deaths attributed to genetic treatments.¹²³

A recent lawsuit in Massachusetts demonstrates another kind of disclosure issue associated with gene therapy. Roger Darke agreed to participate in an experimental gene therapy treatment for chronic heart disease, which required injection of a healthy gene directly into his heart. Less than 24 hours after undergoing the procedure, he died. A lawsuit was later filed alleging that the doctor performing the procedure and the hospital where it was performed were liable because they failed to disclose a financial stake in the gene therapy treatment that gave them an incentive to encourage patients to submit to the treatment. The doctor and the hospital argued that this theory was legally invalid, because the doctrine of informed consent only requires disclosure of medical information. The Superior Court of Massachusetts disagreed, finding that the informed consent doctrine is "broad enough" to require a doctor to disclose "that he has a financial interest in the treatment that he recommends."¹²⁴

Of course, the principle of informed consent raises additional issues when children are involved. It is generally agreed that gene therapy's first, and perhaps only, clear clinical success has been in treating children with a severe immunodeficiency, commonly called "bubble boy syndrome." "In the past six years, the technique has restored the immune systems of 22 children" with the syndrome.¹²⁵ However, three of

the children in one of the gene therapy trials developed leukemia; one died in 2004. It is believed that the virus used to deliver the healthy gene accidentally activated a cancer-causing gene.¹²⁶ All of this raises questions about the ability of parents to make voluntary and informed decisions under duress when dealing with a child who is critically ill and perhaps dying.¹²⁷ Complicating the issue is the fact that most gene therapy trials are early phase studies that focus on safety, not treatment or efficacy. Thus, at this point, “[t]he potential for benefit” from participating “is very low.”¹²⁸ Making this fact clear to parents has been identified as a “key concern” of gene therapy researchers.¹²⁹ As one medical ethicist put it, “[p]arents will always have hopes for their sick children, but participation in gene transfer research should not be offered in ways that exploit those hopes.”¹³⁰

In the sports world, gene therapy raises an entirely different kind of problem: gene doping. Using gene therapy, researchers have been able to genetically engineer mice with super strength. Their goals are to find a way to treat muscle-wasting diseases like muscular dystrophy, and to counteract the muscle weakening that happens to all of us as we age. But so far, the greatest interest in their research has come from the world of sports. According to one researcher, in the six years after he published his first results, he received an average of three emails a week from athletes and coaches looking for a competitive edge; “[t]he inquiries surge every time another advance is announced.”¹³¹ As one sportswriter recently put it, genetic modification through gene therapy “looms as the ultimate supplement. Improvement seems guaranteed and permanent, and there is no test to catch users.”¹³² In the eyes of many, gene doping could result in “the death of sports as we know it.”¹³³ Unfortunately, most experts also agree that it is not a question of whether, but when; if gene doping has not already occurred, it almost certainly will, and probably soon. For this reason, in 2002, the World Anti-Doping Agency began trying to develop a test to detect gene doping. And earlier this year, in his testimony on steroid use in baseball, Don Fehr, the Executive Director of the players union, told the United States Congress that gene doping is “something which bears the closest scrutiny.”¹³⁴

Of course, stem cell research is also very controversial, principally because most techniques for obtaining stem cells involve destroying an embryo in the process. And, to create the “patient specific” stem cells that were announced in August 2005, the South Korean scientists used cloned embryos. Thus, both cloning and stem cell research present us with difficult moral choices.¹³⁵

In February 2002, the United Nations Ad Hoc Committee On The Convention To Ban Human Cloning met for the first time, and heard experts testify about the science and ethics involved.¹³⁶ Singapore, England, Taiwan, and Germany ban cloning and allow limited stem cell research. Here in the United States, several states have outlawed human cloning.¹³⁷ Since 1997, over 40 bills have been introduced in the United States Congress seeking to ban or regulate cloning research.¹³⁸ All of these attempts failed because of disagreements over whether to allow cloning for research purposes.¹³⁹ However, at least since 1997, the use of federal funds for cloned embryo research has been prohibited.¹⁴⁰ In 2001, President Bush authorized the use of federal funds for research on existing stem cell lines.¹⁴¹ The United States Senate passed a bill in 2005 that would expand federal funding for stem cell research. The bill remains pending in the House of Representatives, and faces a threatened presidential veto even if passed.¹⁴²

California’s Legislature has weighed in on this debate through several laws and resolutions. One of those laws indefinitely extends California’s existing ban on human reproductive cloning.¹⁴³ But another law expressly declares that stem cell research “shall be permitted” in California, and directs health care providers to present those receiving fertility treatments “with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research.”¹⁴⁴ Under this law, donations for purposes of research require written consent, and sales for research purposes are strictly prohibited.¹⁴⁵

In passing these laws, the California Legislature made an explicit policy declaration that “[s]tem cell research offers immense promise for developing new medical therapies” for “[a]n estimated 128 million Americans” who “suffer from the crippling economic and psychological burden of [various] chronic, degenerative, and

acute diseases.”¹⁴⁶ At the same time, the Legislature also expressly recognized that stem cell research raises significant and profound ethical, medical, social and legal concerns that must be carefully considered and balanced in formulating public policy.¹⁴⁷ For this reason, the Legislature established a new panel—made up of representatives from medicine, human biology, cellular microbiology, biotechnology, law, bioethics and religion—to study these concerns and advise the Legislature on how to pursue stem cell research “responsibly.”¹⁴⁸ The Legislature also established a separate new committee—made up of independent bioethicists and representatives from medicine, religion, biotechnology, genetics, law, and the general public—to advise the Legislature and the Governor on human cloning.¹⁴⁹

But, the California Legislature did not stop at the California border in trying to guide policy in this area. In 2002, it also passed a resolution urging Congress and the President to “reject legislation that inappropriately impedes the progress of medical science by impeding stem cell and therapeutic cloning research, and denies Americans legal access to effective medical therapies.”¹⁵⁰ The resolution declares that “[t]herapeutic cloning promises to be the next field of rapid progress in the realm of biotechnology,” that “[s]tem cell research has immense potential to provide medical therapies to cure and treat [a number of] debilitating diseases,” and that “embryonic stem cells hold far more potential than adult stem cells as to the development of [such] treatments and cures.”¹⁵¹ Therefore, the resolution continues, a ban on stem cell research and therapeutic cloning would “stifle scientific innovation, diminish the ability of biomedical companies to maintain the nation’s role as the reigning world leader in biotechnology and biomedicine, drive talented scientists outside the country, and set the United States decades behind other nations in the development of medical therapies,” thus “deny[ing] over one-third of Americans their foremost opportunity for a cure or effective treatment for disease.”¹⁵² According to the resolution, “[p]roposed federal legislation that imposes barriers to this research prioritizes the religious values of a national minority ahead of the public interests of Californians and all Americans, criminalizes the legitimate pursuit of effective medical therapy, and prevents physicians from fulfilling their moral and

professional obligation to offer patients the best treatment available.”¹⁵³ The resolution concludes by urging the United States Congress and the President to “ban . . . reproductive cloning,” but to “[p]ermit research involving therapeutic cloning, including the derivation or use of stem cells from whatever source,” to “[e]stablish a process [that] facilitate[s] the donation of material containing stem cells to researchers and ensure[s] that this material is donated by informed participants who provide written consent,” and to “[e]stablish guidelines . . . ensur[ing]” that stem cell research in the United States “is safe and is conducted with appropriate medical, ethical, and moral parameters.”

Of course, there are many who disagree with the views of the California Legislature. In fact, there probably was a good deal of disagreement voiced in the California Legislature during the debate on these laws and resolutions. But, if nothing else, these pronouncements of the California Legislature show, without question, that cloning and stem cell research are likely to be contentious subjects for quite some time because they raise for some the same spiritual and ethical issues that fuel the debate over abortion.

In 2004, California voters also weighed in on the debate, by passing Proposition 71. The initiative created the California Institute for Regenerative Medicine to distribute almost \$3 billion dollars from the sale of bonds over the next ten years for research into developing medical therapies using stem cells. Some have said that Proposition 71 “could make [California] a world leader in one of the most promising, though controversial, fields of biology, perhaps touching off a new biomedical Gold Rush.”¹⁵⁴ However, that rush has already been stifled by litigation. Three lawsuits—two in state court and one in federal court—have been filed challenging various aspects of the proposition, including its constitutionality. These lawsuits, which have effectively blocked the bonds from being issued, may substantially delay implementation of Proposition 71.¹⁵⁵ The Institute is trying to obtain short-term bridge financing from a variety of sources, and is already evaluating almost 30 proposals for the first round of grants—a three-year, \$45 million initiative to train stem cell researchers.¹⁵⁶

The controversy over Proposition 71 is a good example of the delicate and sometimes contentious relationship between science and the law. Scientists are primed and ready to develop cures based on stem cell research. However, their progress depends to some extent on how the courts interpret the constitutional issues related to Proposition 71. Ultimately, there may be a nonjudicial, scientific light at the end of this tunnel. In August 2005, scientists at Harvard University announced a potential breakthrough that could eventually end the controversy over stem cell research: a technique for turning ordinary skin cells into patient-specific embryonic stem cells without either creating or destroying human embryos.¹⁵⁷ However, in announcing their discovery, the Harvard researchers emphasized that there are several technical problems with the new technique that remain to be solved.¹⁵⁸

Of course, because these advances in genetic research use stem cells and human tissue, they pose a host of other new legal questions. As products of human genome research move into the marketplace, how does society address attempts to commercialize products developed from an individual's genetic information? How do the laws of intellectual property apply? Do donors have a right to know that their tissue and cells are being used? Do they have a privacy interest in this material? Do they have an ownership right in this material, or in any discovery or product derived from research on this material? In a famous California case 15 years ago, the California Supreme Court held that an individual has no ownership right in cells and tissue after their extraction, and has no right to know of post-operative research or economic value in the cells, unless the doctor has a direct interest in them that undermines his or her fiduciary duty to the patient.¹⁵⁹

New genetic technology also is forcing the medical community to address the tension between a physician's duty of confidentiality to the patient and a duty of disclosure to others who may have a medical need to know genetic information about the patient. Should doctors inform a patient's relatives of genetic conditions that may affect them, even if the patient objects?¹⁶⁰ What is the ethical answer to this question? What is the medical answer? What is the legal answer? Are the answers different?

In 1996, one New Jersey court took its turn at providing the legal answer to this question in a case involving a woman who had colon cancer that spread through her body.¹⁶¹ When she looked at the medical records of her late father, she discovered he had died from the same hereditary condition. She sued her father's physician for failing to warn her of her predisposition to the condition.¹⁶² The New Jersey court found that physicians do have a duty to warn individuals known to be at risk of avoidable harm from a genetic condition.¹⁶³

REPRODUCTIVE SCIENCE

A similar problem involves ownership of donated reproductive cells. In 2003, an English judge ruled that the legal father of a woman's twins was not her husband, with whom she was raising the children, but the man whose sperm was mistakenly used to fertilize her eggs.¹⁶⁴ In a California case, the girlfriend and children of a deceased man waged a will contest over sperm the man left in a sperm bank for his girlfriend to use in getting pregnant. A California appellate court held that the sperm was a "unique form of 'property'" that sprang from the man's "fundamental right to procreate with whom he chooses," and therefore could only be distributed as he had intended.¹⁶⁵ Of course, the court's decision raises almost as many questions as it answers. For example, what would be the inheritance rights of a child born to the man's girlfriend using his sperm? Similar cases have become common. In Massachusetts, a woman who was artificially impregnated with her deceased husband's sperm had twin daughters, and then applied for mother's and children's social security survivor benefits.¹⁶⁶ The Supreme Judicial Court of Massachusetts held that the twins could inherit if the woman established their genetic relationship to her former husband and that before his death, he consented to support any children reproduced posthumously.¹⁶⁷ In New Jersey, after a couple divorced, the man sought to have a surrogate mother bear a child using cryogenically preserved pre-embryos the couple had earlier created. The New Jersey Supreme Court refused to allow the procedure, finding that it would violate the woman's fundamental right not to procreate.

Earlier this year, a “new frontier” apparently opened in the legal landscape involving preserved embryos.¹⁶⁸ In February, a judge in Chicago ruled that a pre-embryo is a human being, and that a fertility clinic that accidentally destroyed a frozen embryo could be sued for wrongful death.¹⁶⁹ The judge based his ruling on an Illinois statute that says an “unborn child is a human being from the time of conception and is, therefore, a legal person.”¹⁷⁰ If the ruling stands, it could have a tremendous legal impact, not just for U.S. fertility clinics already storing an estimated half million frozen embryos, but for everyone involved in genetic research.¹⁷¹

The availability of more information during pregnancy can also have major repercussions. Suppose a woman who is considering pregnancy is tested to determine whether she carries genetic traits that could harm her child. The test is negative and the woman becomes pregnant, but the child is born severely deformed. The laboratory made a mistake. The woman sues the laboratory, claiming she based her decision to have a child on the results of the testing. Is the laboratory liable? Is the answer different if the test, even when done properly, correctly identifies harmful traits only 30 percent of the time?

What are the child’s rights; can he or she sue for so-called “wrongful life” injuries?¹⁷² A child with a genetic disorder who files a “wrongful life” claim may allege that the doctor did not properly conduct genetic screening tests that would have revealed hereditary genetic defects. As a Maryland court recently explained, a “wrongful life claim is based on the premise “that an impaired existence is worse than nonexistence,” that “being born, and having to live, with the affliction is a disadvantage and thus a cognizable injury, when compared with the alternative of not being born at all.”¹⁷³ Many courts characterize this kind of claim as being “nearly theological [in] nature.”¹⁷⁴ Although four states, including California, permit limited “wrongful life” recovery, 35 expressly prohibit it—25 by case law and 10 by statute.

In August 2002, a California appellate court was presented with an unusual variation of the typical “wrongful life” claim in a case involving a child, a sperm bank,

and several different aspects of genetic technology. The child sued the sperm bank, alleging that its improper screening of the donor who provided the sperm her parents used to conceive her resulted in her birth with a genetic kidney disease. The court concluded that her claim was essentially one for “wrongful life.” It therefore followed the California rule that applies in “wrongful life” cases, which prohibits recovery of general damages, including lost earnings and pain and suffering, but allows recovery of extraordinary expenses to treat the hereditary ailment.¹⁷⁵

These cases demonstrate the difficult challenges confronting us as genetic technology progresses. We will no doubt see more of these claims as our ability to predict genetic disorders continues to improve. Unfortunately, few standards exist for this kind of testing. We need guidance sooner rather than later, because we are already facing questions that only a few years ago seemed unimaginable – and we are grappling for answers.

AGRICULTURAL AND ENVIRONMENTAL BIOTECHNOLOGY

Genetic science is also having a tremendous impact in agriculture, through increasing use of genetically modified organisms. Existing organisms can be endowed with new properties by giving them a gene from another organism.¹⁷⁶ We have already seen crops genetically modified to survive better in droughts or frosts, to stay fresh longer, to resist insects and diseases, and to tolerate herbicides, which allows farmers to spray weed-killer on fields without crop damage.¹⁷⁷ Common examples of this process include delayed-ripening tomatoes and rice enriched with vitamin A.¹⁷⁸ In August 2005, scientists completed a seven-year project to map the complete genome for rice, which is the principal source of calories for about half of the world’s population.¹⁷⁹ Using this information, they hope to produce new plant strains that resist drought and disease, and that grow in colder climates and at higher elevations.¹⁸⁰ Eventually, genetically modified microorganisms may be developed that increase the geographic range of crops by helping control soil conditions.¹⁸¹ The same biotechnological tools can be used with livestock to produce healthier, faster-growing animals, and to improve the quality and quantity of milk, eggs, meat, and wool.¹⁸²

In the United States, the use of genetically modified organisms is already widespread.¹⁸³ By the beginning of the new millennium, more than 60 million acres of United States farmland were covered with genetically engineered crops, including the majority of U.S. soybean and cotton fields and a quarter to a third of U.S. corn fields.¹⁸⁴ Worldwide, by 2004, 167 million acres were planted with genetically engineered crops,¹⁸⁵ representing roughly 25% of all crops. These numbers are staggering, considering that genetically engineered crops were not planted commercially until 1995.¹⁸⁶

Scientists are also developing a process called molecular farming, or “biopharming.”¹⁸⁷ In this process, plants are genetically engineered to contain drugs that can either be extracted and given to a patient or delivered directly simply by having the patient eat the plant. Biopharming is far less costly than current laboratory techniques and its global implications are significant.¹⁸⁸ If made widely available, genetically engineered pharmaceuticals and medical treatments can potentially improve the health and well-being of millions of people worldwide who suffer from treatable diseases and conditions.¹⁸⁹

Biotechnology may also have a significant impact in environmental protection. At first glance, environmental biotechnology may seem like the newest branch of this emerging science.¹⁹⁰ Compared to agricultural and medical biotechnology, environmental research and biotechnological applications seem relatively recent.¹⁹¹ But in truth, we have already been using biotechnology to preserve the environment for thousands of years. For example, composting is a form of biotechnology, in which living organisms break down organic matter and return nutrients to the soil.¹⁹² The practice originated at about the same time agriculture began, when we turned from hunting and gathering our food to tilling fields and growing crops.¹⁹³ Thus, environmental biotechnology and agricultural biotechnology developed during the same time continuum.¹⁹⁴

What is new is modern environmental biotechnology, which inevitably resulted from the advent in the 1970s of genetic engineering.¹⁹⁵ Environmental biotechnology and

modern biotechnology have been interwoven ever since.¹⁹⁶ For example, one of the landmarks in modern biotechnology occurred in 1980 when the United States Supreme Court allowed the award of a patent to Dr. Ananda Chakrabarty for a genetically modified bacteria capable of digesting oil.¹⁹⁷ Released into an oil spill, Chakrabarty's bacteria contain and degrade the environmental hazard faster and more efficiently than naturally-occurring bacteria by feeding on the oil and simultaneously breaking down several of its components.¹⁹⁸

Since Chakrabarty designed his bacteria in 1972, thousands of useful microbes have been isolated and used to treat domestic sewage, industrial waste water, and other environmental pollutants. For example, in 1990, after the Exxon Valdez's oil spill in Alaska, microbe-enhanced fertilizers were used to help clean oil debris off of beaches and shorelines. In a process called bioremediation, the microbes essentially fed upon large, complex, harmful molecules, and broke them down into smaller, harmless ones.¹⁹⁹ Because of bioremediation's great potential to enhance environmental safety more efficiently and at less cost than traditional clean-up methods, scientists are looking for ways to genetically engineer bacteria for greater reliability and to expand the number of pollutants we can treat with this process.

Despite these potential benefits, agricultural and environmental use of modern biotechnology remains highly controversial. The public and many scientists fear that genetic engineering poses unprecedented risks to the environment and to human health and safety.²⁰⁰ For example, concern exists that a previously-benign microbe might accidentally be transformed into a human pathogen that produces dangerous toxins or causes cancer.²⁰¹ Concern also exists that crops genetically engineered for greater resistance to pesticides or herbicides, and weeds or other harmful species to which these traits have been inadvertently transferred, could out-compete native species and reduce biodiversity, unintentionally harm insects and wildlife, and disrupt natural ecosystems.²⁰² These concerns are heightened because, unlike hazardous chemicals or wastes, genetically modified organisms can both spread—because they have “legs”—and proliferate.²⁰³ From a human health perspective, many fear that genetically engineered

foods, which some critics derisively refer to as “Frankenstein Foods” or “Frankenfoods,” could contain new allergens or toxins or produce harmful and unforeseen secondary effects, such as resistance to antibiotics.²⁰⁴ Thus, the use of genetically engineered plants and microbes in agriculture and environmental cleanup presents many unanswered questions, and the benefits of using modern biotechnology in these ways cannot blind us to the potential risks to both human health and the environment.

Many biotechnology companies and their trade associations, United States government officials, and others interested in using biotechnology such as farmers, doctors, and industrial waste managers, assert that current regulation in the United States is adequate to protect human health and the environment.²⁰⁵ Others assert that the existing regulatory framework was not created with genetic engineering in mind and is inadequate to deal with the potential risks of this new technology.²⁰⁶ The regulatory challenge is to control the potential risks without unduly burdening biotechnological development.²⁰⁷

CONCLUSION

This paper has touched on only a few of the issues raised by progress in bioscience—issues that our society must be prepared to confront. As promised, it has identified more questions and problems than answers and solutions. Medical necessity, privacy, and the risk of discrimination, often come into conflict. Scientists, lawyers and judges will be in the forefront of society’s attempt to grapple with these issues. If history teaches us anything, it is that scientific progress is inevitable and unrelenting—and it will certainly overwhelm us if we are not prepared. It is my belief and my hope that if we begin to pose these questions, we will be much better prepared to find reasonable solutions to the complex problems that genetics will certainly bring to our courts.

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