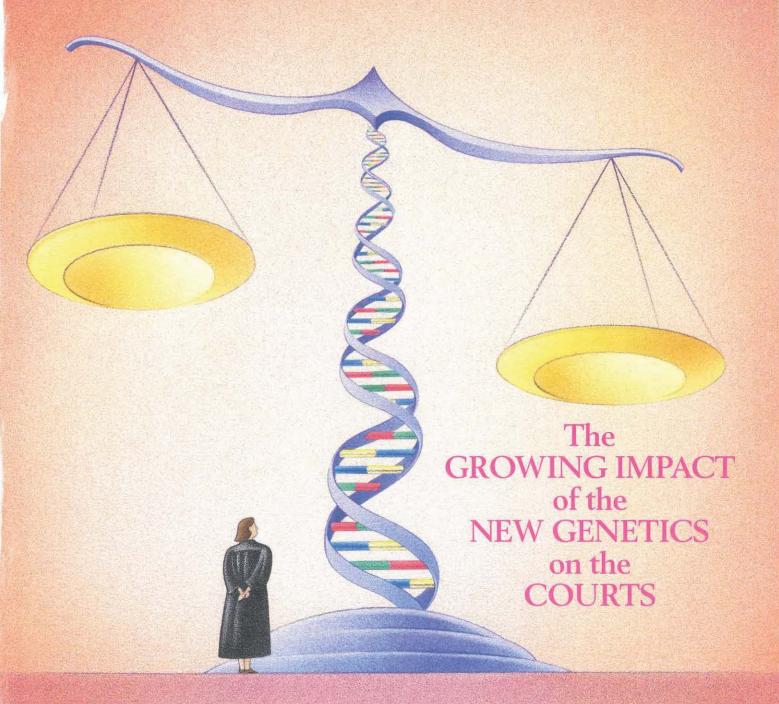


Judicature

NOVEMBER-DECEMBER 1999 VOL 83 NO 3



GENES AND JUSTICE

American Judicature Society

to promote the effective administration of justice

The American Judicature Society promotes the ef-

fective administration of justice at all levels. To this end, AJS publishes this journal and other literature, conducts and disseminates empirical research, produces educational programs, and maintains an information service. AJS also operates the Elmo B. Hunter Citizens Center for Judicial Selection, the Center for Judicial Independence, and the Center for Judicial Conduct Organizations. AJS membership is open to anyone who supports the improvement of the nation's courts.

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Editorial

Eliminating unnecessary delays in filling federal judicial vacancies

The executive branch and the Senate must act to resolve what has become a crisis in democratic government.

Omething terribly wrong has happened to the fed-Deral judicial selection process. That process has become prolonged and politicized to the point that the independence and the integrity of the judicial branch of government are being seriously compromised. The problem is not a new one. We have written before about the corrosive effect that delays in nominations and advice and consent can have on the administration of justice. However, the problem is now acute, as was documented in 1996 by a bipartisan commission sponsored by the Miller Center of Public Affairs at the University of Virginia and most recently by a report issued by the bipartisan Citizens for Independent Courts.

Both the United States Senate and the executive branch share responsibility for the crisis, although perhaps not in equal degree. But apportionment of blame is not the issue. Rather, the legal community and all concerned Americans must make clear to our politicians that it is simply not tolerable

- for vacancies on the bench to exist on average for close to one year before a nomination is sent to the Sen-
- for the Senate Judiciary Committee to refuse to hold hearings on some nominees and to drag out the process on others;
- for the Senate Majority Leader to refuse to schedule, or arbitrarily to delay, a vote on some nominees who have cleared the Senate Judiciary Committee;

Editorials are prepared by a committee of the American Judicature Society appointed by the president.

 for the process to take, as it did in the last Congress, on average 201 days for the Senate to advise and consent.

Of course there are multiple participants and stages in the selection process. And control of the Senate by one political party and of the executive branch by another is also a mighty contributor to the crisis.

Although the crisis may be lessened somewhat by a return to unified government, that is by no means a certainty and does not appear to us to be a solution to the long simmering problem of delay. There are steps that the executive branch and the Senate should take to resolve this crisis in democratic government now and to ensure that it does not recur. They include:

- The average time from vacancy to nomination should be cut in half so that the process to that point does not take more than half a year. The executive branch should devote the necessary resources to promptly identify, evaluate, and process nominees to fill vacancies. To that end, senators of the President's party should be put on notice that if they fail to recommend one or more persons to fill a vacancy within two months from the date of that vacancy (less when there is advance notice of a judge taking senior status or retiring), then the administration will proceed with its own candidates.
- The Senate Judiciary Committee should hold hearings on ALL nominees. No senator, even one from the nominee's state, should be able to prevent the committee from holding a hearing. Of course the committee can vote not to recommend and even not to send the nomination to the Senate floor. The wishes of home state senators can be respected by fellow senators if they so desire. But the Senate Judiciary Committee should do its constitutional duty by voting a nominee up or down.
- The Senate Majority Leader should schedule a timely vote on all nominees sent to the floor by the Senate Judiciary Committee. By allowing one or more senators to place (sometimes secret) holds on nominees, the Majority Leader is subverting the constitutional directive that the Senate advise and consent. The Senate must do its constitutional duty and vote to confirm or reject the President's nominees.
- If the Senate consistently fails in its responsibilities, the President should use the check and balance in the Constitution of making recess appointments. Recess appointments of judges was a common practice until the Reagan Administration. Some 300 judges over the course of the nation's history first went on the bench as recess appointees, including Chief Justice Earl Warren and Associate Justice William Brennan. They received their appointments not because of an impasse with the Senate, but because it was necessary to have a full strength judiciary. But our history reveals instances when recess appointments were used in impasse situations, such as the recess appointment of Thurgood Marshall to the U.S. Court of Appeals for the Second Circuit.

Business cannot continue as usual. The judicial branch deserves better, and the people deserve better, than the combination of neglect and partisan politics that now threatens our constitutional democracy.

From the President of the American Judicature Society

Dear Readers:

Sandra Ratcliff Daffron, who served as Executive Vice President and Director of the American Judicature Society since 1997, submitted her resignation effective November 1, 1999.

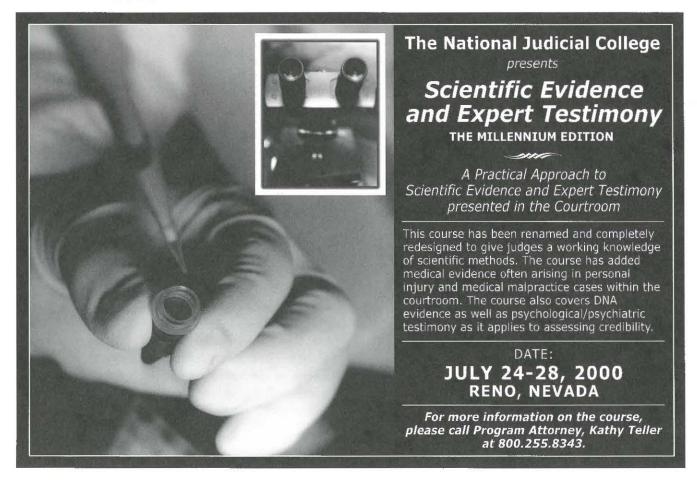
Sandy, and her husband John Daffron Jr, a circuit court judge in Chester-field County, Virginia, will lead a project team in Israel beginning in January 2000. The project will work to develop improvements in the civil and criminal justice system, provide assistance to law schools, establish model court pilot projects in Gaza and the West Bank, create an alternative dispute resolution program annexed to the judicial system, and provide assistance to the judge's association. The Daffrons will also assist with the implementation of a Palestinian judicial council and a judicial institute that will provide the foundation for a more effective and independent judicial branch.

We wish Sandy and John well in this endeavor.

Cean Reed Haynes

Jean Reed Haynes

President



Foreword

by Shirley S. Abrahamson

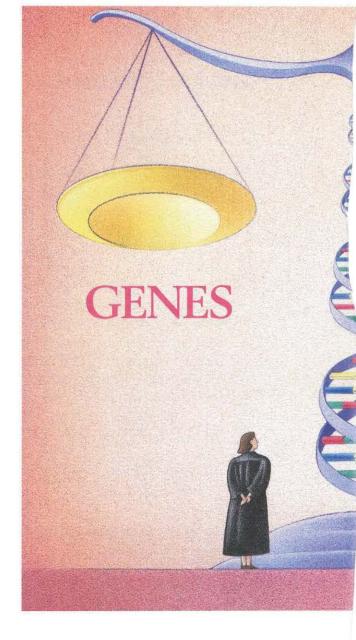
n the July-August 1998 issue of *Judicature*, U.S. Supreme Court Justice Stephen Breyer writes about the interdependence of science and law. He notes that "law itself increasingly needs access to sound science" and that scientifically complex technology "increasingly underlies legal issues of importance to all of us." Justice Breyer reminds us that "a judge is not a scientist and a courtroom is not a scientific laboratory" but that "to do our legal job properly we [need] to develop an informed, though necessarily approximate, understanding of the state of…relevant scientific art."

This issue of *Judicature* addresses the interdependence of the fields of genetics and law and relations between the legal and the scientific communities. Over the last decade we have witnessed amazing scientific advances in genetic information, and more is yet to come. As the Human Genome Project now nears completion, we are only beginning to assess the impact that advances in human genetics will have on the legal system and on society.

DNA technology is becoming increasingly integrated into our judicial system, especially in the criminal justice system. DNA analysis has proved to be a powerful tool to identify perpetrators and to exonerate the innocent. The assimilation of DNA technology into criminal trials comes just as the role of the judiciary as gatekeeper in assessing scientific evidence is changing.

The use of DNA technology to match a crime scene profile to a suspect profile has presented one set of issues. The potential use of DNA information as a predictor of or explanation for behavior will create a new, more complex set of concerns. Databanks of genetic material will raise weighty questions of ownership, access, confidentiality and privacy beyond the questions suggested in the context of criminal DNA databases.

While criminal courts will find themselves addressing the expanded role of forensic genetics, civil courts will also struggle with increasingly difficult problems raised by genetic information. For example, gene mapping is producing unprecedented insight into the causes of disease. Decisions about what constitutes "having" a particular disease as compared with being "predisposed" to contracting



a disease may have a significant impact on insurance, medical malpractice, product liability, and other health and employment issues that come before the courts.

This issue of *Judicature* discusses some impacts these enormous scientific advances will have on our legal system and on society. It is said that biotechnology, including genetics, will be to the 21st century what computer technology was to the 20th. Thus the approach the legal system takes to integrate genetic information is critical. We must, as Justice Breyer writes, "build legal foundations that are sound in science, as well as in law...to resolve many of the most important human problems of our time."

All of us are indebted to the American Judicature Society and *Judicature* for the publication of these articles considering these important issues.

SHIRLEY S. ABRAHAMSON is Chief Justice of the Wisconsin Supreme Court and chair of the National Commission on the Future of DNA Evidence.

AND

e stand on the cusp of one of the most exciting and rapid expansions ever of knowledge about life's inner most secrets. By late spring, scientists in the international Human Genome Project (HGP) expect to deliver a rudimentary map of 90 percent of human DNA—the chemical blueprint that contains the information required to create and maintain all life's structures and activities. The HGP, cosponsored in this country by the Department of Energy (DOE) and National Institutes of Health, aims to complete a detailed human DNA map by 2003, along with genetic maps of other organisms.

Advances in DNA science already have led to revelations across all kingdoms of life on earth, from animals and plants to the hidden worlds of

Introduction

by Denise K. Casey, Symposium issue editor

microscopic bacteria and viruses, all of which use DNA to encode life instructions. Potential applications of the new genetic tools and data are broad and diverse. They offer a dazzling array of possible benefits to humanity but also raise many ethical, legal, and social dilemmas that are beginning to arrive at the courts for resolution.

This symposium issue of *Judicature*, sponsored in part by the DOE component of the HGP, focuses on the growing societal impact of DNA technology and some of the genetics-related issues that courts will confront in the near future.

In "Genes, dreams, and reality: The promises and risks of the new genetics," I offer a brief primer on the basics of DNA science and the HGP and provide an overview of the controversies surrounding gene testing, one of the first commercialized applications of HGP data. This article also presents a glimpse into the potential benefits and pitfalls of an astonishing array of other current and future applications of DNA technology.

The genetics of human behavior and traits such as intelligence is a topic of long-standing fascination. Do genes influence us to be aggressive, shy, or depressed? Vulnerable to substance abuse? Proficient (or hopeless) in math or languages or art? Can we predict, prevent, or choose the future development of these traits in ourselves or others? "Genes and behavior: A complex relationship" by Joseph D. McInerney explains how scientists know that genes do indeed play a role in behavior, but the complex interplay between multiple genes and environmental factors is only beginning to be deciphered.

In "The impact of behavioral genetics on the law and the courts" by Mark A. Rothstein, the author observes that in the past the law has succumbed to cultural pressures to facilitate and legitimize "genetic determinism"—a mistaken belief that genes are the sole determinants of behavior. The article goes on to frame the legal issues surrounding behavioral genetics and suggests how the law might be expected to respond to new discoveries.

DNA technology will someday enable us to change the physical and possibly the behavioral characteristics of ourselves and future generations. "The Human Genome Project and the courts: Gene therapy

This issue of *Judicature* is presented in its entirety on the Internet at the Human Genome Project Information web site (www.ornl.gov/hgmis) sponsored by DOE. Visit this site for a wealth of information on the HGP and related genetics applications.

and beyond" by Maxwell J. Mehlman examines a broad range of potential issues arising from enhancement technologies. It predicts that courts will be called on to settle an array of disputes involving patients, health care professionals, institutional providers, insurers and other third-party payers, and the government. Some issues include access; safety of human experimentation; new expectations for standard of care for healthcare providers in a dynamic, unsettled scientific environment; and parental vs. child rights.

Applying traditional patenting practices to biological materials such as genes presents some interesting issues, particularly in terms of health policy goals, and society may need to search for ways to merge ethical with business concerns. "Hope, fear, and genetics: Judicial responses to biotechnology" by E. Richard Gold discusses such considerations as whether patents increase or stifle innovation in biotechnology and encourage particular types of research over others, as well as concerns over the sometimes conflicting interests of patients and companies owning gene patents.

"Keeping the gate: The evolving role of the judiciary in admitting scientific evidence" by Joseph T. Walsh examines the increasing burden on judges to keep "junk science" out of the courtroom. The expanded gatekeeper role is the result of the 1993 decision of the United States Supreme Court in *Daubert v. Merrill Dow Pharm., Inc.*, together with more recent refinements. The article discusses post-*Daubert* developments and some problems arising in their application as cutting-edge science evolves.

"From crime scene to courtroom: Integrating DNA technology into the criminal justice system" by Christopher H. Asplen presents the goals of the National Commission on the Future of DNA Evidence. The Commission's purpose is to determine how the Department of Justice can best encourage the effective use of DNA identification technology in postconviction proceedings as well as in crime scene investigations. The article describes the enormous potential value—and the challenges—of implementing the newly established database [Combined DNA Index System (CODIS)] for fighting crime. CODIS stores identification data on DNA samples from offenders convicted of particular crimes. Both the United Kingdom and China have similar databases.

Jurors must be better prepared to cope with the increasingly complex issues if they are to evaluate contradictory opinions of expert witnesses and properly apply the law to the evidence presented. "Complex scientific evidence and the jury" by Rob-

ert D. Myers, Ronald S. Reinstein, and Gordon M. Griller offers a practical guide to jury reform as pioneered in Arizona, where the role of juror has been redefined from passive observer to active participant in the trial process.

Preparing judges to carry out their duties effectively in adjudicating cases of increasing scientific and technical complexity is a growing concern. "Educating judges for adjudication of new life technologies," by Franklin Zweig and Diane E. Cowdrey, presents an evaluation of one conference from a series of workshops aimed at introducing judges to some of the scientific and societal issues raised by genetics.

As Yogi Berra once observed, "The future ain't what it used to be." Hovering on the horizon are genetic technologies that will endow us with new powers to change and literally shape all forms of life at their most basic levels. The dilemmas presented in this issue represent only a sampling of the challenges that society will face as we apply genetic knowledge in ways we cannot even imagine today. Projects sponsored by the ethical, legal, and social issues components of the U.S. HGP begin to anticipate these issues, but the dialogue must grow to encompass all sectors of society worldwide as we move cautiously toward a new and exciting future armed with the keys to the kingdom of life.

DENISE K. CASEY (caseydk@ornl.gov) is a science writer, editor, and educator with the DOE Human Genome Program at Oak Ridge National Laboratory. She has written numerous articles for technical and lay readers on genetics and its applications and has served as a faculty member at judicial education seminars.

GENES, DREAMS, AND REALITY The promises and risks of the NEW GENETICS

by Denise K. Casey

Researchers in the worldwide Human Genome Project are deciphering the order of the 3 billion subunits of human DNA—work that offers many potential benefits along with some novel and challenging issues.

eadlines about DNA, genes, and the new powers of scientists to analyze and manipulate these fundamental elements of life vie for our attention daily. The dazzling diversity of applications of DNA science to fields ranging from medicine and agriculture to forensics and environmental restoration undoubtedly will have resounding impacts on society and each of our own lives.

Many of the new genetic discoveries stem from data and tools generated by the massive international Human Genome Project (HGP), whose goal is to describe in intricate detail the DNA from humans and other selected organisms by 2003. Because DNA is the information molecule that carries instructions for creating and maintaining all life, resources

For more information about the Human Genome Project and related genetics issues, contact Denise Casey at the Human Genome Management Information System (HGMIS; 865/574-0597; caseydk@ornl.gov) or access the HGMIS Web page (www.ornl.gov/hgmis). Sponsored by the U.S. Department of Energy's Human Genome Program, this site features a comprehensive collection of information on the Human Genome Project, explanatory material on genetics, and links to a wealth of related information. The articles in this issue are also on the site.

and analytical technologies generated by the HGP and other genetic research can be applied to the DNA of all organisms on earth. Other important HGP goals are to develop tools for data analysis and to address some of the ethical, legal, and social issues that may arise from the project.

This article offers some basic information on the Human Genome Project and DNA science that will help the reader understand why genetic information is so powerful. It also describes a few current applications and some developments we can expect to see in the next few years, and

presents some of the potentially troubling societal concerns surrounding this work.

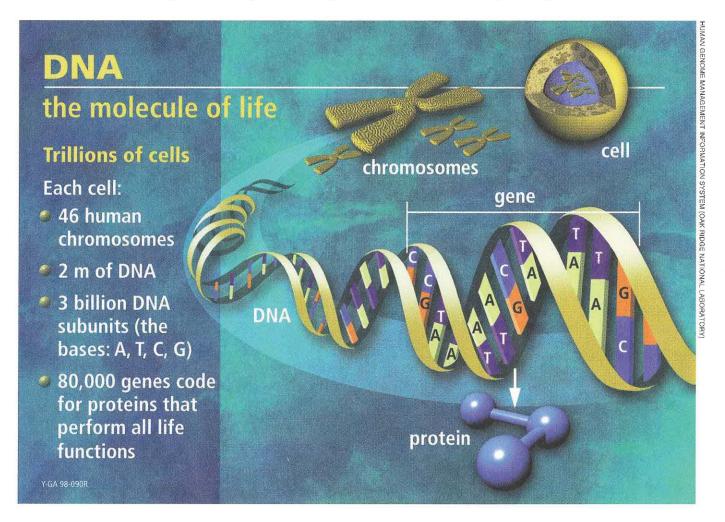
DENISE K. CASEY is a science writer, editor, and educator with the DOE Human Genome Program and guest editor of this symposium.

The Human Genome Project

The HGP began in 1986 as a way for scientists in the U.S. Department of Energy (DOE) to use newly developing DNA analytical technologies to fulfill a long-standing mandate from Congress to assess the health effects

of radiation. For decades DOE and its predecessors have developed international standards for the use of advanced medical diagnostic tools and treatments involving radiation and the protection of workers in the federal and civilian nuclear industry.

As the potential benefits of human genetics research became more apparent, Congress requested that DOE and the U. S. National Institutes of Health develop a joint genome project. The U.S. Human Genome Project began formally in 1990 with expanded goals to describe all hu-



Societal concerns of the "new genetics"

Fairness in the use of genetic information by insurers, employers, courts, schools, adoption agencies, and the military, among others.

Privacy and confidentiality of genetic information.

Psychological impact and stigmatization due to an individual's genetic differences.

Reproductive issues including adequate informed consent for complex and potentially controversial procedures, use of genetic information in reproductive decision making, and reproductive rights.

Clinical issues including the education of doctors and other health service providers, patients, and the general public in genetic capabilities, scientific limitations, and social risks; and implementation of standards and quality-control measures in testing procedures.

Uncertainties associated with gene tests for susceptibilities and complex conditions (e.g., heart disease) linked to multiple genes and gene-environment interactions.

Conceptual and philosophical implications regarding human responsibility, free will vs genetic determinism, and concepts of health and disease.

Safety and environmental issues concerning genetically altered foods and microbes.

Commercialization of products including property rights (patents, copyrights, and trade secrets) and accessibility of data and materials.

—Denise Casey

man genetic material (DNA) by 2005. However, rapid technological achievements advanced the expected completion date to 2003, and a draft product is eagerly anticipated by 2000. International research teams, particularly those from the United Kingdom but also from France, Germany, and Japan joined U.S. scientists to make significant contributions to the HGP.

Today researchers worldwide are using HGP data and powerful analytical technologies to devise creative applications in an expanding array of fields. The claims and promises of these new capabilities are diverse and

bold. But the new technologies and the data they generate also present complex ethical and policy issues that individuals and society, including the courts, have begun to confront (see "Societal concerns of the new genetics," page 106).

A brief glossary

The following primer will help ground the reader

in the terms used throughout this article. It may also be helpful to refer to the figure on page 106.

Genome. A genome is a complete set of coded instructions for making and maintaining an organism. It is made up of the chemical DNA.

Chromosome. The complete human genome is packaged into 46 pieces of DNA called chromosomes. Humans receive a set of 23 chromosomes from each parent. A complete set of 46 chromosomes is found in almost every one of our trillions of cells. Most cell types—skin, bone, hair, brain, heart—contain a complete human genome. Exceptions are sperm and egg cells, which contain 23 chromosomes, half the amount of DNA found in other cells; and mature red blood cells, which lack DNA.

DNA. DNA is the chemical that stores coded information on how, when, and where an organism should make the many thousands of different proteins required for life. DNA

contains four different chemical building blocks called bases and abbreviated A, T, C, and G. In humans and other higher organisms, a DNA molecule consists of two strands of DNA whose bases connect with each other to form base pairs (see figure). With the exception of identical twins, each person's sequence of DNA bases—the order of As, Ts, Cs, and Gs along a single DNA strand—is different. This is what makes each person unique.

Genes. A gene is a piece of DNA that contains instructions for building a particular protein. Proteins are essential for all aspects of life. All or-

Untangling the genetic and environmental contributions to complex disease will be one of the greatest challenges for medical researchers in the next century.

> ganisms are made up largely of proteins, which provide the structural components of all cells and tissues as well as specialized enzymes for all essential chemical reactions. Through these proteins, our genes dictate not only how we look but also how well we process foods, detoxify poisons, and respond to infections.

> Genes constitute only a tiny fraction, a mere 3 percent, of our DNA. The gene (coding) regions in our DNA are interspersed among millions of noncoding DNA bases whose functions are still largely unknown. Scientists estimate that we have from 80,000 to 100,000 genes whose sizes range from fewer than one thousand to several million bases.

DNA and disease

For all our apparent outward diversity, humans are surprisingly alike at the DNA level. We differ by only one or two tenths of one percent of our DNA—some three to six million bases—yet these tiny DNA variations

are responsible for all our physical differences and may influence many of our behaviors as well.

Most DNA variation among individuals is normal, but harmful variations called mutations can cause or contribute to many different diseases and conditions. Depending on their size and where in the DNA they occur, mutations can have devastating effects or none at all. If they occur within genes, the result can be the creation of faulty proteins that function at less-than-normal levels or are completely nonfunctional and result in disease.

All diseases have a genetic basis.

We may inherit a particular condition, such as the lung disease cystic fibrosis, or an increased likelihood for developing such disorders as heart disease or colon cancer. We also inherit the particular ability to respond to such environmental stresses as viruses, bacteria, and toxins. Understanding how DNA influences every aspect of health even-

tually will lead to far more effective ways to treat, cure, or even prevent the thousands of diseases that afflict humankind.

Some 4000 rare diseases are due to a single mutation in a single gene. These include cystic fibrosis, sickle cell anemia, and Tay Sachs. The causes are much more complex for common disorders such as heart disease, diabetes, hypertension, cancers, Alzheimer's disease, schizophrenia, and manic depression. These diseases are thought to be due to a variety of gene mutations, perhaps acting in concert, or to a combination of genes and such environmental factors as diet or exposure to radiation or toxins. Untangling the genetic and environmental contributions to complex disease will be one of the greatest challenges for medical researchers in the next century.

DNA science applied: Medicine and health

Gene tests. DNA-based tests are

Gene tests: the power and the limits

Scanning a person's genes for mutations linked to a particular disease already has saved some lives and dramatically improved others. Some gene tests can alert patients and physicians to an inherited tendency toward a disorder and lead to increased surveillance or other preventive treatments. For example in familial adenomatous polyposis (FAP), a rare form of inherited colon cancer, lives have been saved through testing for the mutated gene linked to FAP and aggressive monitoring for early re-

moval of colon growths or even the entire colon.

Interpreting the meaning of a negative test for the FAP mutation, however, is not straightforward. The possibility of developing the disorder is not ruled out because different mutations may be responsible for the disease in different individuals. However, some physicians who order tests and interpret them for patients are unaware of these subtleties. An article published in the New England Journal of Medicine reported that one-

third of physicians in a study group misinterpreted negative results in the FAP mutation test. If the researchers monitoring the study had not intervened, those doctors would have advised their patients to discontinue aggressive surveillance (colonoscopies), advice that could have had disastrous consequences. Comprehensive education of medical professionals is considered critical to the effective introduction of the new genetics into clinical practice.

-Denise Casey

among the first commercial applications of the new genetic discoveries to medicine. These tests are employed to diagnose a condition or estimate the likelihood for developing one. Test results already are being offered as evidence to support medical and nonmedical cases in courts, including medical malpractice, discrimination, privacy violations, child custody disputes, and criminal cases.

Gene tests involve direct examination of the DNA molecule itself. A DNA sample can be obtained from any tissue, including blood. To do a gene test, scientists scan the sample, looking for a specific mutation in a particular DNA region that has been linked to a disorder. Cost can range from hundreds to thousands of dollars, depending on the sizes of the genes examined and the number of mutations tested for, which can vary from a few to hundreds. Although there are several hundred DNAbased tests for different conditions. most are still offered as research tools only. Fewer than 100 gene tests are available commercially, and most are for mutations associated with rare diseases in which just a single gene is involved (see "Some currently available gene tests," page 110).

Even though some current gene tests have been beneficial and their potential benefit enormous, the science is very new and dynamic. Researchers themselves are unsure how to interpret the results of some commercially available gene tests (see "Gene tests: the power and the limits," above).

Another limitation is the lack of medical options to treat or prevent many of the disorders for which gene tests are used. Researchers acknowledge the long lag time between linking a gene mutation with a disease and developing effective therapeutics. Additionally, patients agreeing to undergo gene testing face significant risks of jeopardizing their employment and insurance status. Patients face an additional burden as well: the psychological impact of testing can be devastating. Because genetic information is shared, all these risks extend to family members as well.

Many in the medical establishment feel that uncertainties surrounding test interpretation, the current lack of available medical options for most of these discases, the potential for provoking anxiety, and the risks of discrimination and social stigmatization could outweigh the early benefits of testing (also see "Who's regulating gene tests," page 111).

Preventive medicine and customized therapies. Studies of gene function will lead to a deeper understanding of normal biological processes

and how they go awry in disease states. These insights will allow the development of better and earlier predictive tests and eventually usher in a field of prevention-based medicine and diagnostics.

Within the next decade, researchers also will begin to understand how DNA variations underlie our individual responses to medical treatments. Tens of thousands of people are hospitalized each year as a result of toxic responses to medications that are beneficial to others. Some cancers respond dramatically to current therapeutic regimens while the same treatment has no effect on disease progression in others. Scientists in major pharmaceutical companies are trying to sort out the specific regions of DNA associated with drug responses, identify particular subgroups of patients, and develop drugs customized for those populations. These capabilities are expected to make drug development faster, cheaper, and more effective while drastically reducing the number of adverse reactions.

Drug design itself will be revolutionized as researchers use gene sequence and protein structure information to create new classes of medicines based on a reasoned approach rather than the traditional trial-and-error methods for finding new drugs. The new drugs, targeted to specific sites in the body and to particular points in the cascade of biochemical events leading to disease, will likely cause fewer side effects than many current medicines. Ideally, they would act earlier in the disease process.

Gene therapy and genetic enhancement. The potential for using genes themselves to treat disease has captured the imagination of the public and the biomedical community. This rapidly developing field—called gene transfer or gene therapy—holds great potential for treating or even curing such genetic and acquired diseases as cancers and AIDS by using normal genes to replace or supplement defective genes or bolster a normal function like immunity.

Over 350 clinical gene-therapy trials are now in progress worldwide, most for different kinds of cancers. Performed on patients in advanced stages of disease, most current studies aim to establish the safety of genedelivery procedures rather than determine their effectiveness. The technology itself still faces many obstacles before it can become a practical approach for treating disease; however, novel experimental approaches look very promising (see "Gene therapy: using genes to treat disease," below).

Besides preventing and treating inherited and infectious diseases, genetransfer technologies probably will make possible the enhancement or replacement of genes that influence other traits such as height, weight, strength, stamina, and even intelligence. These capabilities will generate many questions about the regulation of such technologies and the fairness of access to these expensive protocols, as well as safety and privacy issues, among others.

"Pharming" animals to produce human drugs. Gene-transfer technologies already are being used to transfer human genes into farm animals such as sheep and goats for the purpose of generating large quantities of expensive human proteins for use as pharmaceuticals. (The process has been called "pharming.") The animals carrying human genes are called "transgenics" and are very difficult and expensive to develop. This situation has encouraged biotechnology companies to explore more efficient ways to reproduce the animals; cloning technologies such as those used to create the famous Scottish sheep Dolly and other cloned mammals like mice, goats, and cows are the results of these efforts. And a reasonable assumption is that many of the new reproductive technologies being perfected in our mammalian cousins will be effective in—and applied to—humans.

Xenotransplants: from pigs to people. Some 18,000 organ transplants take place each year, not nearly accommodating the 40,000 who wait for appropriate donors. Ten people die each day waiting for suitable human donor organs. Transplanting such organs as hearts and

kidneys from genetically altered pigs and other animals into humans, a process called xenotransplantation, may have the potential to save lives. Current research is aimed at using DNA technologies to grow organs having human genes that make the organ's surface more "human like" and may help to minimize the chance for rejection upon transplantation into a human host. A concern is the unintended transfer of animal viruses to humans and the effects this might have beyond the patient to the population at large.

Identification

Multiple uses across species. DNA technology can be used to identify any type of organism, from humans and whales to plants, viruses, and bacteria. One important use is for identifying organisms contaminating soil, air, water, and food. Pinpointing a disease source in an epidemic, for example, is critical for its rapid control. These analyses are not limited to diseases affecting humans: they can be used to identify disease sources in livestock, poultry, and plants as well.

Some uses of human DNA identification are to establish paternity and other family ties in adoption and immigration cases, identify victims of wars and other catastrophes, and aid the courts in criminal cases where biological evidence (e.g., blood and sperm) is left behind. Interestingly, DNA data gathered from other species present at a crime scene, such as plants, dogs,

Gene therapy: using genes to treat disease

One of the most intriguing applications of genetic research is the use of genes themselves to treat, cure, and ultimately prevent disease. The science of gene therapy is in its infancy, however, and the goal of most current clinical trials is only to demonstrate the procedure's safety, not its

effectiveness. A partial listing follows of diseases that are the focus of clinical gene-therapy trials.

Canavan disease Cystic fibrosis Familial hypercholesterolemia Gaucher's disease Hemophilia B
Various advanced cancers
HIV infection
Coronary artery disease
Rheumatoid arthritis
Hematological malignancies
(leukemias)

—Denise Casey

cats, and viruses (HIV) also have been used as evidence in trials.

A controversial DNA databank. In July, police linked a dead Florida man's DNA to eight unsolved rapes in Washington, using only the data available from a national DNA databank, called CODIS (Combined DNA Index System). No other investigative leads were available. CODIS, which came online in late 1998, contains DNA descriptions, or "profiles," of offenders convicted of certain serious crimes. While many agree that this use of DNA technology can be of great benefit to society, one controversy surrounding DNA profiling stems from the potential of a DNA sample to reveal much more about an individual (and their family) than just their identity. While today's practices scan specific DNA regions that do not currently reveal such additional information, the human genome is still relatively unknown territory, and no one knows

what types of information future technology may be able to uncover from stored samples.

Another source of concern over DNA databanking is the potential for expanding the use of databases beyond that originally intended. Thought-provoking historical examples of expanding database functions include the now pervasive social security number system that was originally started in the 1930s to help with a newly established retirement program, and the use of census records to round up Japanese-Americans for placement in interment camps during World War II.

Agriculture and animals

Stronger cotton, healthier livestock. For thousands of years people have modified traits in plants and animals indirectly through selective breeding. Today, our growing ability to directly alter an organism's genetic makeup, called genetic engineering,

is having a major impact worldwide on agriculture and animal husbandry. A number of ongoing projects aim to decipher and manipulate the genomes of such economically important organisms as rice, corn, wheat, soy, cotton, sheep, goats, cows, pigs, and fish.

Some of these explorations have led to the development of genetically modified plants that are providing higher yields, are more nutritious, and have increased resistance to herbicides, pests, and extremes of weather and temperature. In the United States this year, about half of all soybeans and a third of all corn planted were from genetically modified seeds, with most modifications aimed at pest and herbicide resistance.

Genetic alterations have produced ornamental crops such as carnations whose "aging genes" have been identified and turned off to allow an extended shelf life. Other plants are

Some currently available gene tests

Gene tests for the disorders listed below are available from clinical genetics laboratories around the country. (Test name and some symptoms appear in parentheses.) The gene tests currently available (most in research settings only) detect only rare conditions that are usually caused by DNA changes in a single gene. Such common diseases as hypertension, heart disease, diabetes, and many cancers have complex genetics probably involving several genes that interact with environmental conditions to cause disease. There are no gene tests for these conditions yet, but this undoubtedly will change as more is learned about DNA.

- Amyotrophic lateral sclerosis (ALS; Lou Gehrig's Disease; progressive motor function loss leading to paralysis and death)
- Gaucher disease (GD; enlarged liver and spleen, bone degeneration)

- Inherited breast and ovarian cancer (BRCA1 and 2; early-onset tumors of breasts and ovaries)
- Hereditary nonpolyposis colon cancer (CA; early-onset tumors of colon and sometimes other organs)
- Cystic fibrosis (CF; disease of lung and pancreas resulting in thick mucous accumulations and chronic infections)
- Duchenne muscular dystrophy/ Becker muscular dystrophy (DMD; severe to mild muscle wasting, deterioration, weakness)
- Fanconi anemia, group C (FA; anemia, leukemia, skeletal deformities)
- Fragile X syndrome (FRAX; leading cause of inherited mental retardation)
- Hemophilia A and B (HEMA and HEMB; bleeding disorders)
- Huntington disease (HD; usually midlife onset; progressive, lethal, de-

generative neurological disease)

- Neurofibromatosis type 1 (NF1; multiple benign nervous system tumors that can be disfiguring; cancers)
- Adult Polycystic Kidney Disease (APKD; kidney failure and liver disease)
- Prader Willi/Angelman syndromes (PW/A; decreased motor skills, cognitive impairment, early death)
- Sickle cell disease (SS; blood cell disorder; chronic pain and infections)
- Spinocerebellar ataxia, type 1 (SCA1; involuntary muscle movements, reflex disorders, explosive speech)
 - Thalassemias (THAL; anemias)
- Tay-Sachs Disease (TS; fatal neurological disease of early childhood; seizures, paralysis)

—Denise Casey

Who's regulating gene tests?

Most gene tests are offered as clinical laboratory services (rather than self contained "kits"), and while the U.S. Food and Drug Administration (FDA) has the authority to regulate such services, it has chosen not to because of a lack of resources. Although the quality of a laboratory to perform a test accurately is regulated under the Clinical Laboratory Improvement Amendments of 1988, no regulations exist that require evidence of a particular gene test's clinical validity (the probability that a person who tests positive will actually develop the disease) or it's utility (the potential for preventing or delaying the development of the disease in a person with a positive test). People who are educated in these medical uncertainties are less likely to choose gene testing when they are weighing their benefits against the possibilities of discrimination by insurers, employers, schools, and others.

Some companies have exaggerated both the validity and clinical utility of current gene tests in their eagerness to market these first commercial products of the "new genetics." Although most current gene tests are used to diagnose or predict a risk for developing rare diseases, testing for susceptibility to more common diseases-like heart disease and diabetes—is the largest category of tests under commercial development. We can expect that aggressive marketing

(some have called it "genohyping") will increase with the widening spectrum of tests developed, and some may in fact be offered directly to the public, a situation already occurring in the United Kingdom.

The Secretary's Advisory Committee on Genetic Testing (www.nih.gov /od/orda/sacgtdocs.htm) of the U.S. Department of Health and Human Services is presently exploring these and other medical, scientific, ethical, legal, and social issues raised by the development and use of genetic tests. The committee has also sought public perspectives on these issues as it prepares its recommendations, which are due in the spring.

—Denise Casev

being genetically modified to produce biodegradable plastics, industrial oils and chemicals, low-calorie sweeteners, and human pharmaceuticals. Genetically modified animals are more nutritious and leaner, produce more milk, and are sometimes larger and more resistant to disease.

In a few recent examples, researchers reported adding rabbit genes to cotton plants to make the fiber as bright and soft as rabbit hair but stronger and warmer. A new strain of rice announced this spring contains a soybean gene for iron incorporation. This new rice can be used to treat the 30 percent of the world's population who are iron deficient and lack the means for expensive iron supplements.

Growing concerns. Consumer resistance to genetically modified plants and resulting foods, sometimes called "Frankenfoods," is strong in Europe and may be growing in the United States. Concerns center around environmental and consumer safety issues. Particularly in the United Kingdom, the strength of resistance to

genetically modified foods stems from a lack of trust in the government to protect its citizens, following the "mad cow" disease scare.

Although genetically modified plants can decrease the use of pesticides and herbicides and thereby benefit the environment, a concern is that plants engineered to be more resistant to herbicides may pass on that trait through cross-pollination to related weed species in the wild. This could result in the creation of extremely resistant weeds requiring treatment with even more herbicides. Also, the impact of new pestresistance traits on such nontarget organisms as visiting butterflies or birds is not known.

A potential health concern is that genes producing allergy-inducing proteins (such as those from peanuts) could be introduced into other food plants and consumers might unknowingly ingest a substance to which they could be allergic. (In the United States, the federal government is considering voluntary labeling of products derived from genetically modified organisms.) Another controversial issue is that genes introduced from one species into another may cause some consumers to violate religious restrictions against, for example, eating pork or beef.

A careful balance

Genetic data and tools offer enormous potential benefits to humankind but pose significant risks as well. As the impact of the new genetics grows, we can expect the courts to be increasingly confronted with many novel, challenging, and sometimes disturbing issues.

Scientific progress continues to advance rapidly as society scrambles to keep apace. But no one can anticipate some of the ways current and ever more powerful future DNA technologies will be put to use, nor their unintended and potentially controversial or adverse effects. As we begin to realize the benefits of the new genetics, maintaining a cautious approach will help minimize the risks. 44

GENES AND BEHAVIOR

A complex relationship

by Joseph D. McInerney



Rottweilers have a reputation for being vicious. But is such behavior inbred in their genes or is the environment more important in shaping actions?

ometimes lessons in biology come unexpectedly, as when a rottweiler appeared over my right shoulder while I was kneeling to trim some rose bushes early this summer. He was large—

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more so for being at eye level—and he was wearing a collar made of chain links large enough to anchor a small ship. I turned to face him as an archive of rottweiler news stories came up from long-term memory, none of them happy, all of them populated by mutilated people and by dogs destroyed at the direction of the authorities.

What to do next? How did I appear to this animal? Did I look like a threat? Did I look like lunch? He certainly wasn't behaving in a menacing manner, but maybe he was waiting for the right moment to express his breed's well-known, vicious disposition. One of us had to do something, I figured, although reason, the pride

I am grateful for a helpful review of this article by Barton Childs, M.D., Johns Hopkins Hospital.

Although scientists agree on a connection between genes and behavior, the likelihood that we soon will use genetic analysis to accurately predict behavior or explain a criminal act is not great.

of Homo sapiens, was little comfort in the face of the evolutionary legacy of Canis familiaris: powerful jaws and teeth adapted to gripping and tearing. I extended my hand slowly, and—he licked it. The dog worked his way up to my face with a tongue as broad and soggy as a kitchen sponge, and, as his owner appeared, I expressed my relief at seeing such friendly behavior from a representative of so notorious a breed. The young man replied, "These dogs get a bad rap. People say they're born mean. Look at Caesar, here. Ain't no dog born mean. You got to teach them to be mean."

In their different ways, Caesar and his human friend raised long-standing questions about the roots of animal behavior, including behavior in our own species. Are behaviors inbred, written indelibly in our genes as immutable biological imperatives, or is the environment more important in shaping our thoughts and actions? Such questions cycle through society repeatedly, forming the public nexus of the "nature vs. nurture controversy," a strange locution to biologists, who recognize that behaviors exist only in the context of environmental influence. Nonetheless, the debate flares anew every few years, reigniting in response to genetic analyses of traits such as intelligence, criminality, or homosexuality, characteristics freighted with social, political, and legal meaning.

Sir Francis Galton (1822-1911) was

The ideal criminal has marked peculiarities of character: his conscience is almost deficient, his instincts are vicious, his power of self-control is very weak, and he usually detests continuous labor. The absence of self-control is due to ungovernable temper, to passion, or to mere imbecility, and the conditions that determine the particular descriptions of crime are the character of the instincts and of the temptation.

The perpetuation of the criminal class by heredity is a question difficult to grapple with on many accounts.... It is, however, easy to show that the criminal nature tends to be inherited

The true state of the case appears to be that the criminal population receives steady accessions from those who, without having strongly marked criminal natures, do nevertheless belong to a type of humanity that is exceedingly ill suited to play a respectable part in our modern civilization, though it is well suited to flourish under half-savage conditions, being naturally both healthy and prolific.1

This passage demonstrates Galton's conviction about the hereditary basis of criminal behavior, by no means established even now, but he wrote elsewhere in the same volume about the "difficulty of distinguishing that part of (man's) character which has been acquired through education and circumstance, and that which was in the original grain of his constitution." The difficulty persists, notwithstanding an explosion of data about human genes and the development of molecular and statistical tools that Galton could not have imagined.

Behavioral genetics

The term "genetics" did not even appear until 1909, only two years before Galton's death, but with or without a formal name, the study of heredity always has been, at its core, the study of biological variation. Human behavioral genetics, a relatively new field, seeks to understand both the genetic and environmental contributions to individual variations in human behavior. That is not an easy task, for the following reasons.

• It often is difficult to define the behavior in question. Intelligence is a classic example. Is intelligence the ability to solve a certain type of problem? The ability to make one's way successfully in the world? The ability to score well on an IQ test? During the late summer of 1999, a Princeton molecular biologist published the results of impressive research in which he enhanced the ability to learn in mice by inserting a gene that codes for a protein in brain cells known to be associated with memory. Because the experimental animals performed better than controls on a series of traditional tests of learning, the press dubbed this gene "the smart gene" and the "I.Q. gene," as if improved memory were the central, or even sole, criterion for defining intelligence. In reality, there is no universal agreement on the definition of intelligence, even among those who study it for a living.

Having established a definition

the first scientist to study heredity and human behavior systematically. He focused on behavioral correlations within families and developed a few research techniques still in use today—twin studies, for example. Galton also arrived at some interesting conclusions, including this 1907 summary of the inheritance of criminal tendencies:

^{1.} Galton, Inquiry into Human Faculty and its DEVELOPMENT, 2nd edition (London: J.M. Dent & Sons, Ltd., 1907).

for research purposes, the investigator still must measure the behavior with acceptable degrees of validity and reliability. That is especially difficult for basic personality traits, such as shyness or assertiveness, which are the subject of much current research. Sometimes there is an interesting conflation of definition and measurement, as in the case of IQ tests, where the test score itself has come to define the trait it measures. This is a bit like using batting average to define hitting prowess in baseball. A high average may indicate ability, but it does not define the essence of the trait.

- Behaviors, like all complex traits, involve multiple genes, a reality that complicates the search for genetic contributions.
- As with much other research in genetics, studies of genes and behavior require analysis of families and populations for comparison of those who have the trait in question with those who do not. The result often is a statement of "heritability," a statistical construct that estimates the amount of variation in

a population that is attributable to genetic factors. The explanatory power of heritability figures is limited, however, applying only to the population studied and only to the environment in place at the time the study was conducted. If the population or the environment changes, the heritability most likely will change as well. Most important, heritability statements provide no basis for predictions about the expression of the trait in question in any given individual.

Research in behavioral genetics proceeds from the assumption that behavior is rooted in biology, a conclusion shared by all biologists and obvious even to the nonspecialist after a few moments of reflection (see "Indications that behavior has a biological basis," page 115). Simply accepting that conclusion, however, is a lot easier than elucidating underly-

ing biological mechanisms. Furthermore, even casual observation tells us that biology is not the whole story. If it were, there would not be discrepant phenomena such as schizophrenics whose identical twins—naturally occurring clones—are unaffected by the disease, or Caesar, the antithesis of his bad-tempered rottweiler cousins.

Traditional research strategies in behavioral genetics include studies of twins and adoptees, techniques designed to sort biological from environmental influences. More recently, investigators have added the search for pieces of DNA associated with

Behaviors, like all complex traits, involve multiple genes, a reality that complicates the search for genetic contributions.

particular behaviors, an approach that has been most productive to date in identifying potential locations for genes associated with major mental illnesses such as schizophrenia and bipolar disorder. Yet even here there have been no major breakthroughs, no clearly identified genes that geneticists can tie to disease. The search for genes associated with characteristics such as sexual preference and basic personality traits has been even more frustrating.

Such are the allure and misunderstanding of genetics among press and public, however, that even preliminary findings of genetic influence provoke misleading statements about "genes for" a particular behavior, as if genetic causation had been established. In fact, genes can do nothing by themselves. All of their actions and influence are mediated by proteins—gene products—and until we

understand something about the proteins involved in the myriad steps that produce a given trait, and about the individual uniqueness to which they contribute, it is difficult to propose a plausible biological explanation for the trait's expression. The uniqueness is compounded by the non-linear nature of those myriad steps. Indeed, pervasive uniqueness suggests that there is no fixed essence in human behavior, only variation, a concept central to all of biology and one that Galton's famous cousin, Charles Darwin, used to build his revolutionary theory of evolution by natural selection.

> To this already complex calculus we must add the knowledge that biological processes that combine to produce behaviors or any other complex traits cannot exist apart from the unique experiences of the individual, perhaps dating as far back as experiences in the womb. An accounting of those experiences and of their interactions with one's unique biological constitution would confound our ability to make sound predic-

tions about the occurrence of a given behavior, even if we knew that predisposing genes were present.

Some progress

Genetics and molecular biology have provided some significant insights into behaviors associated with inherited disorders. For example, we know that an extra chromosome 21 is associated with the mental retardation that accompanies Down's syndrome, although the processes that disrupt brain function are not yet clear. We also know the steps from gene to cffect for a number of single-gene disorders that result in mental retardation, including, phenylketonuria (PKU), a treatable metabolic disorder for which all newborns in the United States are tested.

In general, it is easier to discern the relationship between biology and behavior for chromosomal and

INDICATIONS that BEHAVIOR has a BIOLOGICAL BASIS

- a border collie.

- Behavior has an evolutionary history, as dem-

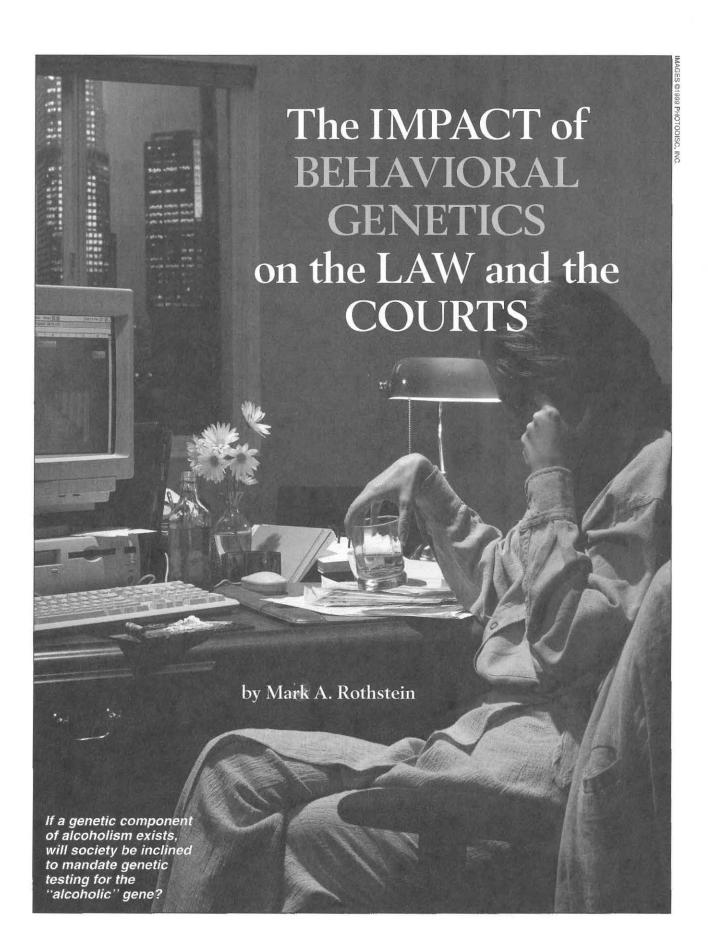
—Joseph D. McInerney

single-gene disorders than for common, complex behaviors that are of considerable interest to specialist and nonspecialist alike. So the former are at the more informative end of a sliding scale of certainty with respect to our understanding of human behavior. At the other end of the scale are the hard-to-define personality traits, while somewhere in between are traits such as schizophrenia and bipolar disorder—organic diseases whose biological roots are undeniable yet unknown, and whose

unpredictable onset teaches us about the importance of environmental contributions even as it reminds us of our ignorance.

The Human Genome Project doubtless will provide researchers with the data they need to identify individual genes or suites of genes that contribute to human behaviors. The really hard work only begins at that point, however, with analysis of the ways in which the products of those genes influence human growth and development, of the environmental

influences on those processes, and of the degree of individuality of both. So, the likelihood that we soon will use genetic analysis to predict the behavior of a given person or to explain a behavior already expressed-a criminally violent act, for exampleis not great. Those who study genes and behavior, however, are confident about one thing: The debate about nature vs. nurture is empty; the prevailing view is one of how nature and nurture contribute to the individuality of behavior. 414



New discoveries in genetics, including behavioral genetics, will raise a host of legal questions requiring careful scrutiny by the courts.

he Human Genome Project, officially begun in 1990 and scheduled for completion between 2000 and 2003, has heralded a period in which genetic factors have been identified for numerous disorders. In addition, researchers in the field of behavioral genetics have asserted claims for a genetic basis of numerous physical behaviors, including homosexuality, aggression, impulsivity, and nurturing. A growing scientific and popular focus on genes and behavior has contributed to a resurgence of behavioral genetic determinism—the belief that genetics is the major factor in determining behavior. This could lead to grievous social consequences.

Research in behavioral genetics has been extremely contentious. There are several scientific obstacles to correlating genotype (an individual's genetic endowment) and behavior. One problem is in defining a specific endpoint that characterizes a condition, be it schizophrenia or intelligence. Another problem is in identifying and excluding other possible causes of the condition, thereby permitting a determination of the significance of a supposed correlation. Much current research on genes and behavior also engenders very strong feelings because of the potential social and political consequences of accepting these supposed truths. Thus, more than any other aspect of genetics, discoveries in behavioral genetics should not be viewed as irrefutable until there has been substantial scientific corroboration.

Flawed scientific theories can be refuted by more rigorous science. A more perplexing social quandary involves the permissible societal response to legitimate discoveries in behavioral genetics. Undoubtedly, there is some correlation between certain genes and behavioral traits. The only serious scientific dispute concerns the overall degree of correlation and the applicability of genetic factors in a range of specific behavioral traits. What, then, are the likely psychological, social, political, and legal consequences of such correlations?

As an example, take the case of alcoholism. Several past and ongo-

ing studies have explored whether there is a genetic component of alcoholism. Assume such a component exists in some cases of alcoholism. Does that mean that, as a society, we will be more or less tolerant of alcoholics, more or less inclined to mandate genetic testing to detect a particular version of a gene or genes (called "alleles"), or more or less likely to embrace a disease model for this behavior?

On the one hand, it could be argued that the genetic component decreases the moral taint attached to individuals with alcoholism. On the other hand, the genetic, heritable nature of the disorder may increase the stigma, it may increase the pressure for genetic screening for the particular allele, it may contribute to individuals feeling a sense of resignation and a reluctance to enter treatment, and it may lead to disdain for individuals who, despite knowledge of their genotype, continue to drink.

Similar issues are raised with regard to a possible genetic link to homosexuality. If we find a "gay gene," will it mean greater or lesser tolerance? My suspicion is that it will not change the way most people view homosexuals. For individuals who are tolerant of homosexuals, it will reaffirm that the behavior is physiologically based and does not represent moral depravity. For those less tolerant of homosexuality, it will confirm their view that such individuals are

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minism: Its Effect on Culture and Law, in Behavioral Generics: The Clash of Culture and Biology, 89-115. Ronald A. Carson & Mark A. Rothstein, eds. (Johns Hopkins University Press 1999). Reprinted by permission of the publisher.

^{1.} Hamer and Copeland, Living with our Genes 144 (New York: Doubleday, 1998).

[&]quot;abnormal." It also could lead to proposals that those affected by the "disorder" should undergo treatment to be "cured" and that mea-

sures should be taken to prevent the birth of other individuals so afflicted.

Genetic determinism and the law

One consequence of new genetic research may be a resurgence of behavioral genetic determinism. If so, this phenomenon would have major implications for the legal system. I have written elsewhere at length about the effects of genetics on many areas of law, including employment, insurance, commercial transactions, civil litigation, and privacy.2 Rather than discussing specific areas of the law in which behavioral genetics may be important, I will discuss five general principles of law that help to frame the issues of behavioral genetics and the law.

1. The law has established a unitary standard for determining an individual's legal duty. In both the civil and criminal law, the lawfulness of an individual's conduct is determined by reference to the standard of behavior of a reasonable person. The hypothetical reasonable person is not the average person or the average juror, but the personification of a community ideal of reasonable behavior. This is an objective and largely unitary standard.

The reasonable person standard, originally expressed as the "reasonable man" standard, was first applied to negligence law in England in the middle of the nineteenth century.3 The concept was soon adopted in the United States.4 By the beginning of the twentieth century the genderneutral "reasonable person" came into use and is now used in every state. The reasonable person standard is often expressed as the reasonably prudent person, or some similar terminology, all of which have the identical meaning. Thus, both plaintiffs and defendants in civil negligence cases have the reasonableness of their conduct evaluated in terms of whether it conforms to the standard of a reasonably prudent person under similar circumstances.

Although the law does not consider minor, individual variations in the character and abilities of the individual in establishing the standard for evaluating conduct, there are some exceptions. Children are held to the standard of a reasonable child of the same age. An individual's special talents or training also are considered.

For example, in a medical malpractice case, the "standard of care" is that of a reasonably prudent physician in good standing in the profession, or if the individual is a specialist, the reasonably prudent physician in a certain specialty. If the individual has a physical impairment, the standard is the reasonably prudent person with the same impairment, such as the reasonably prudent person with blindness. Note, however, that the reasonable person standard generally has not been adjusted for mental impairments or behavioral shortcomings. These matters historically were assumed to be impossible to assess accurately. Moreover, excusing the conduct of people because of their asserted individual inability to conform to the reasonable person standard was seen as an invitation to fraud.

The criminal law also recognizes a version of the reasonable person standard. Criminal negligence is defined by reference to a reasonable person. In cases where a murder has been committed in a moment of passion, a reasonable person standard is used to determine whether the circumstances would cause such a reaction. If so, then the charge of murder is reduced to voluntary manslaughter.

The main rationales for the reasonable person standard are:

- the required conduct of the individual and the outcomes of cases are more predictable,
- having a unitary, objective standard allows individuals to have reasonable expectations of the behavior of others,
 - it is easy for juries to apply,
- it can adapt and change over time,
- it does not need detailed codification.

Inherent in the application of the reasonable person standard is that it is impossible to determine the precise cognitive, physical, or behavioral abilities of the individuals in any given legal proceeding. Notwithstanding this established legal principle, suppose precise evaluation of individual characteristics were possible—or even were believed to be possible. Suppose an expert witness on behavioral genetics were prepared to testify about the innate capability of a specific individual in a civil or criminal proceeding. Would this matter? Should it?

Philosopher Dan Brock frames the issue in the following way. "If a person's genetic structure is a principal cause of behavior and that genetic structure is completely beyond the individual's control, can an individual justifiably be held responsible for the resultant behavior?"5 It is not clear whether or how behavioral genetic discoveries and claims will affect the law's fundamental assumptions about individuals as responsible agents. If the unitary standard were replaced with a more subjective standard, it would cause a significant change in the law's view of the bounds of individual conduct.

2. The adversary system requires lawyers to present all possible arguments on behalf of their clients, especially in criminal cases. The adversary system of adjudicating lawsuits was transported to the American colonies from England. It can be traced to two Renaissance ideas: the attempt to use reason to understand the world; and the concern for human dignity, whereby individuals on trial should have a

^{2.} See Rothstein, Genetic Secrets: A Policy Framework, in Rothstein, ed., Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Eera (New Haven: Yale University Press, 1997); Rothstein, Preventing the Discovery of Plaintiff Genetic Profiles by Defendants Seeking to Limit Damages in Personal Injury Litigation, 71 Ind. L.J. 71 (1996); The Use of Genetic Information for Nonmedical Purposes, 9 J.L. & Health 109 (1995); Rothstein, Genetics, Insurance, and the Ethics of Genetic Counseling, in Friedman, cd., Molecular Genetic Medicine, vol. 2. (San Diego: Academic Press, 1993); Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 Hou. 1. Rev. 23 (1992).

^{3.} Blyth v. Birmingham Waterworks Co., 156 Eng. Rep. 1047 (1856); Vaughan v. Menlovc, 132 Eng. Rep. 490 (1837).

^{4.} See Holmes, THE COMMON LAW 108 (Boston: Little, Brown and Co., 1881)

^{5.} Brock, The Human Genome Project and Human Identity, 29 Hou. L. Rev. 7, 16 (1992).

wide range of defenses available in attempting to avoid conviction.

The adversary system uses a partisan presentation of the evidence, a largely passive judge, a neutral jury, and a structured trial format. The lawyer's role in both criminal and civil cases is not to determine the truth; the truth will be decided by the impartial trier of fact—either the judge or jury. The lawyer's role is to be the zealous advocate of the position of his or her client. Overreaching, implausible, or untruthful assertions by either side are exposed through the cross-examination of witnesses and the presentation of con-

trary evidence. Theoretically, this system not only uncovers the truth, but it results in popular support for the judicial system because parties have a chance to present all of their arguments.

Trial lawyers are not merely permitted to be zealous advocates, they are required to be so by legal ethics. The Model Rules of Professional Conduct provide that a lawyer "has a duty to use legal procedure for the fullest

benefits of the client's cause."6 The lawyer is duty bound to make any lawful argument in support of the client's position "without regard to [the lawyer's] professional opinion as to the likelihood that the construction will ultimately prevail," so long as the argument is not frivolous. In criminal cases, even frivolous arguments may be asserted, the only limitation being that a lawyer may not offer perjured testimony. During the post-conviction, sentencing phase of a criminal case, defendants are given even wider leeway in presenting mitigating evidence.

Innovative scientific assertions come within the "zealous advocacy" principle in criminal cases. One example involves the use of the post-partum psychosis defense in at least 12 U.S. cases in which

mothers were accused of murdering their infants. In most of the cases, the women were found not guilty by reason of insanity or received light sentences, although it is not clear what weight, if any, was given the defense. Premenstrual syndrome and post traumatic stress syndrome also have been asserted as defenses.

For many individuals, the zealous advocacy standard for presenting novel defenses was stretched to the breaking point by the "Twinkie defense" in the murder trial of Dan White, a former San Francisco supervisor charged with murdering Mayor

Behavioral genetic arguments are particularly appealing in criminal cases because they can be used to prove that the defendant was compelled to commit the act by uncontrollable genetic factors.

George Moscone and supervisor Harvey Milk in 1978. At trial, forensic psychiatrist Dr. Martin Blinder, then an assistant clinical professor at the University of San Francisco Medical School, testified that the junk food eaten by White could have affected his decision to shoot the victims. After White was convicted merely of voluntary manslaughter, the California Legislature amended the penal code to limit defense attorneys' right to offer such evidence.

In civil cases, such as personal injury litigation, plaintiffs often have a difficult time proving causation—that their injury was caused by the unlawful act of the defendant. Using what detractors have termed "junk science" or "liability science," scientific experts have pushed the frontiers of scientific thinking in asserting that, for example, a particular environmental exposure, pharmaceutical

product, or medical device resulted in a particular harm to the plaintiff.

Because of the adversary system, it is virtually certain that parties in both criminal and civil cases will assert behavioral genetic arguments well before there is general support for such views in the scientific community. These arguments are particularly appealing in criminal cases because they can be used to prove that the defendant was compelled to commit the act by uncontrollable genetic factors.

3. Judges and juries have little, if any, expertise in evaluating scientific claims. If the adversary system encourages—indeed demands—that

lawyers zealously advocate unproven scientific theories on behalf of their clients, the next important question is how will judges and juries view this evidence? By all indications, both judges and juries are ill-prepared to evaluate the validity of novel scientific assertions, and juries are likely to give too much credence to such arguments.

The initial problem faced by a lawyer in trying to introduce scientific evi-

dence is persuading the court that the proffered evidence is admissible. In an influential 1923 decision, Frye v. United States, the Court held that scientific evidence is admissible if it is generally accepted as valid by the scientific community.

The so-called Frye-test lasted for 70 years, until the Supreme Court's 1993 decision in Daubert v. Merrell Dow Pharmaceuticals, Inc. The Court held that Frye did not survive the enactment of the Federal Rules of Evidence in 1975. Under the Federal Rules, judges cannot defer to the scientific community's acceptance of the evidence in question. Instead, judges are required to make an independent determination of the reliability and probative value of the evidence.

Judges must determine "whether the reasoning or methodology underlying the testimony is scientifically valid." This is composed of four fac-

Model Rules of Professional Conduct, Rule 3.1, Comment I.

tors: (1) whether the theory or techniques can be or have been tested; (2) the extent to which there has been peer review and publication of the theory or techniques; (3) the known or potential error rate and the existence and maintenance of standards controlling the technique's operation; and (4) the general acceptance of the methodology or technique in the scientific community.

Although there is some disagreement among judges and scholars, most believe that *Daubert*, at least in theory, made it easier to get scientific evidence admitted into court. There is no dispute, however, that *Daubert* made things more difficult for trial court judges. According to Judge Jack Weinstein of the United States District Court for the Eastern District of New York:

Many federal judges believe *Daubert* made their lives more difficult. They are going to have to give a more reasoned statement about why they are letting in evidence. They can't do it on a rubber-stamp basis the way some of them did it in the past.... After all, we're not scientists. We're in strange territory and we want to do the best we can.⁷

Although Daubert is not binding on state courts, many state courts have adopted the approach of requiring a more active role for trial court judges in deciding admissibility. At the least, the new responsibilities have caused state court judges to diversify their reading materials to include scientific works. Yet, according to one state court judge, both trial and appellate judges "tend to have no particular training in statistical analysis as it relates to scientific research, unless they worked through doctoral programs in science before making the career switch to law."8 In fact, "they tend to be scientifically ignorant, which means they are not acquainted, let alone conversant, with scientific practice or language."9 To increase the scientific acumen of judges, state and federal court administrators have begun programs of scientific education as well as publication of manuals on scientific evidence. It is not clear how successful these efforts have been.



If we find a "gay gene" will it mean greater or lesser tolerance for homosexuals?

If efforts are under way to educate judges about scientific methodology, no such efforts are being contemplated with respect to jurors. Indeed, the Anglo-American tradition of a lay jury is based on the premise that jurors should be average members of the community and they should not have special expertise. Jurors with expertise in the matters at issue are generally dismissed during jury selection, because lawyers are concerned that the other jurors will defer to the single knowledgeable juror, thereby negating the whole purpose of a jury.

Jurors' lack of scientific expertise has resulted in a demonstrated inability to comprehend scientific evidence. Nevertheless, several studies have documented that jurors tend to put great credence in expert testimony, even though they do not understand it. ¹⁰ A key factor is the persuasiveness of the expert presenting the testimony.

Putting together the factors discussed above produces the following results. The adversary system demands that lawyers introduce scientific evidence that may not have been rigorously tested, judges without scientific expertise must decide whether the methodology and theories have a valid scientific basis, novel scientific evidence is increasingly being found admissible, and juries often give great credence to the evidence even though they usually do not understand it, so long as the expert appears knowledgeable. There is no reason to believe that behavioral genetic information would not fit this pattern as well.

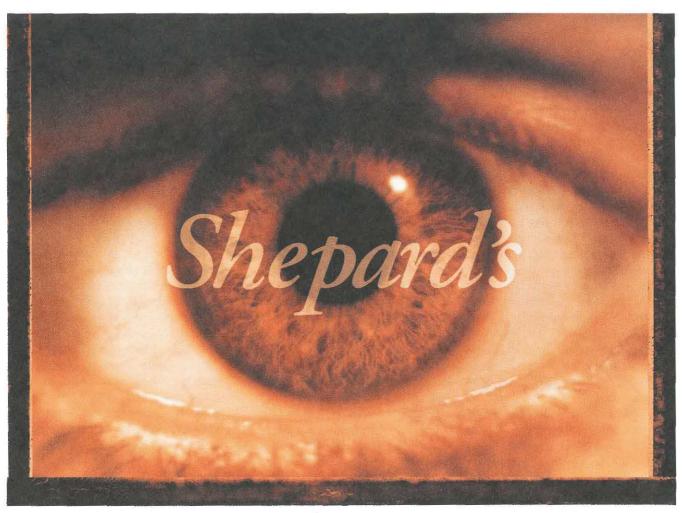
(Editor's note: Efforts to assist judges and juries with scientifically-complex material are discussed in several articles in this issue—"Keeping the gate: the evolving role of the judiciary in admitting scientific evidence" by Joseph T. Walsh; "Complex scientific evidence and the jury" by Robert Myers, et. al.; and "Educating judges for adjudication of new life technologies" by Franklin Zweig and Diane E. Cowdrey.)

4. The law encourages risk-averse behavior. If lawyers are required by legal ethics and encouraged by financial incentives to assert all possible claims for their clients, unproven scientific evidence increasingly is admitted into evidence, and judges and juries generally lack the expertise to

Sherman, "Junk Science" Rule Used Broadly; Judges Learning Daubert, NAT'L I.-J., Oct. 4, 1993, at 3,

^{8.} Gless, Some Post-Daubert Trial Tribulations of a Simple Country Judge: Behavioral Science Evidence in Trial Courts, 13 Behavioral Sci. & L. 261, 263 (1995). 9. Id.

^{10.} Broyles, Taking the Courtroom into the Classroom: A Proposal for Educating the Lay Juror in Complex Cases, 64 Geo. Wash. L. Rev. 714, 721-722 (1996).



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evaluate the evidence critically, what are the effects? Obviously, one effect in personal injury litigation could be to establish the liability of a particular defendant. Another potential consequence is to create a generalized state of risk aversion among other possible defendants.

The concept of "defensive medicine" has been widely discussed. It is difficult to quantify the extent or the effects of medical practices designed primarily to avoid malpractice litigation. Yet, this is merely one manifestation of risk averse behavior caused by concern for tort liability. Other examples include companies ceasing the manufacture of football helmets and the removal of diving boards from public swimming pools. It took an act of Congress, the National Childhood Vaccine Injury Act, to ensure that there would be enough pharmaceutical companies willing to produce vaccines.

In some instances of deleterious environmental health effects, such as those resulting from asbestos and tobacco, the evidence of both industry culpability and causation are overwhelming and irrefutable. In other instances, however, such as the harms allegedly resulting from bendectin and breast implants, the evidence is less clear. Regardless of the scientific community's position on the evidence, the fear of liability often motivates the actions of individuals, institutions, and companies.

Behavioral genetic information could lead to a wide range of riskaverse actions. To illustrate, in a 1994 case a security guard at a Bon Jovi rock concert attempted to rape a 16year-old patron under the stands. The girl then sued the security company that employed the guard for negligent hiring. She alleged that had the company done a background check, it would have discovered that the man had four prior convictions, including one for second degree robbery. In reversing the trial court's granting of summary judgment for the company, the appellate court observed that upon discovery of a prior robbery conviction, a prospective employer would be on notice that the

prospective employee had a propensity for violent behavior. (Carlsen v. Wackenhut Corp., 1994.)

Would employers in the future have a duty to review medical records or conduct their own medical testing to determine whether applicants had genetic indicators of an increased risk for violent behavior? Would it violate the Americans with Disabilities Act or other laws to do so? If behavioral genetic tests were on the market and their use by employers was not unlawful, it is possible that a jury might impose liability for failure to use them, especially in light of the great harms that often befall the plaintiffs in such cases. If there were a single case finding liability, it is easy to imagine other employers being pressured by insurers and the public to require tests of school teachers, day care workers, police officers, home health care workers, and numerous other employees.

It is also possible that behavioral genetic information could be required in other contexts besides employment. For example, suppose a young camper at summer camp unexpectedly and deliberately hit another camper in the head with a baseball bat, causing serious injury. Because statutory liability of parents for the intentional torts of their children is quite limited, and because the child is unlikely to have adequate assets to satisfy a judgment, a negligence action might be brought against the camp. Assuming the children were adequately supervised, the injured child's lawyer might assert that had the camp required behavioral genetic testing of all campers it would have learned that the aggressor child was predisposed to violent behavior. It then could have refused to admit the child, thereby preventing the injury. If the injured child is able to obtain a judgment, or even a settlement, then the risk-averse behavior for every other summer camp, boarding school, college dormitory, and other entities might be to require a review of behavioral genetic test results. Pressure to do so also could come from parents.

These are just two examples of pos-

sible liability avoidance measures that could be used for violent or aggressive behavior. A similar response is also possible for asserted behavioral genetic associations involving substance abuse, impulsivity, homosexuality, or other "predispositions."

5. The law has not done a good job of protecting medical privacy. The recognition of a legal right to privacy is largely a twentieth-century development. In American law, the development has proceeded along three separate lines: constitutional privacy, common law privacy, and statutory privacy. In none of these areas, however, has the privacy and confidentiality of medical information been afforded adequate protection.

The federal constitutional right to privacy is based on the Fourth, Fifth, and Fourteenth Amendments. This right to privacy and related interests, such as liberty and autonomy, have been used to prohibit the government from interfering with personal medical decisions, such as providing and withholding medical treatment, procreation, contraception, and abortion. Federal constitutional rights protect against governmental and not private interference, but a few state constitutions also contain privacy provisions applicable to both the public and private sectors.

Even where federal constitutional law applies to protect privacy, the right to privacy is not absolute and often is considered to be outweighed by other governmental interests. For example, New York enacted a statute requiring that in filling all prescriptions for Schedule II drugs an official form must be completed, including the name of the prescribing physician, dispensing pharmacy, drug and dosage, and the patient's name, address, and age. The form is then filed with the state health department, where the information is entered in a computer and stored for five years. In a unanimous decision, the Supreme Court held that the statutory scheme was a legitimate effort to deal with the serious problem of drug abuse (Whalen v. Roe, 1977). Interestingly, the Court relied on the generally diminished privacy rights of patients to support the view that the governmental intrusion was minimal.

Disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient. Requiring such disclosures to representatives of the State having responsibility for the health of the community, does not automatically amount to an impermissible invasion of privacy.

The second privacy law doctrine, common law invasion of privacy, may be applied to a variety of factual situations. Indeed, the legal doctrine has

evolved into four related torts: public disclosure of private facts, intrusion upon seclusion, false light, and appropriation of name or likeness. The first two are especially relevant to medical privacy.

To establish a claim for invasion of privacy based on public disclosure of private facts, the plaintiff must show dissemination or "publication" of private matters (e.g. medical information) in which the

public has no legitimate concern so as to bring shame or humiliation to a person of ordinary sensibilities. Some parties, such as employers, have been granted a qualified privilege to disclose certain facts deemed essential to their business interests. For example, where work was disrupted at a nuclear power plant because of rumors that the reason for an employee's illness at work was radiation exposure, a Mississippi court held that the employer had a privilege to tell employees that the plaintiff was ill due to the effects of a hysterectomy (Young v. Jackson, 1990).

The other important basis of invasion of medical privacy is intrusion upon seclusion. "One who intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is sub-

11. Restatement (Second) of Torts §652B (1977).

ject to liability to the other for invasion of his privacy if the intrusion would be highly offensive to a reasonable person."11 Individuals who are in a weaker economic position (e.g. employees, insurance applicants) often are compelled to disclose or release medical information. They are often placed in a no-win situation, which is not aided by the common law doctrine. If they refuse to supply information, even if they are discharged as a result, the courts hold that their privacy has not been invaded. On the other hand, if they supply the information, then they have consented to release of the in-

There is no reason to expect that behavioral genetic information will be afforded greater privacy protection than other forms of medical or genetic information.

formation and there is no right to legal redress.

The third main legal method of protecting privacy is statutory. A variety of state and federal statutes attempt to deal with one or more aspects of medical privacy. None of these laws provides adequate protection, however. For example, in 1995 Oregon enacted the nation's first state law designed to protect the privacy of genetic information. Subject to various exceptions, the law provides, among other things, that no person may obtain genetic information from an individual without informed consent, no person may retain genetic information without obtaining specific authorization, and no person may disclose genetic information without specific authorization. A similar "procedural" law has been enacted in California.

What has been labeled "genetic privacy" legislation is, in reality, genetic security legislation. The laws only prohibit the unauthorized collection, retention, or disclosure of genetic information. They have no effect on the myriad instances in which individuals can be required to release genetic and other medical information as a condition of employment, insurance, education, commercial transactions, and other matters.

There is no reason to expect that behavioral genetic information will be afforded greater privacy protection than other forms of medical or genetic information. Some constitutional, statutory, or common law theories may be applied to limit some

> overly intrusive inquiries or unnecessarily extensive disclosures. In general, however, a wide range of substantive limitations in each specific area will need to be enacted to safeguard the privacy of this information.

How will the law respond?

The law does not operate independently of culture, it follows culture. In the 1920s, when eugenics

dominated American scientific thinking, it also dominated American culture and American law. How will the law respond to new discoveries in genetics, including behavioral genetics? To what level of legal scrutiny will claims of behavioral genetics be subjected? How will *proven* associations of genetics and behavior affect a range of legal doctrines related to privacy, autonomy, nondiscrimination, and societal opportunities? How will *unproven* or outright bogus assertions be received by the courts?

Legislative and judicial responses to new genetic discoveries will have a major effect on whether we are about to enter an unprecedented period of behavioral genetic determinism and, with it, social disruption, or the promised enlightened era of genetic marvels. While history does not preordain the future, it certainly reminds us of the stakes involved.

The Human Genome Project and the courts GENE THERAPY AND BEYOND

The courts will be called upon to settle an array of disputes involving genetic medicine among patients, health care professionals, insurers, and the government.

by Maxwell J. Mehlman

he impact of the Human Genome Project will be much broader than just making it possible to test people or to screen populations for genetic disorders. Gene therapies—both in the form of drugs manufactured with genetic technolHundreds of clinical trials are underway to test the safety and efficacy of gene therapy to treat disorders such as cystic fibrosis and Parkinson's disease.¹

So far, these new technologies are limited to producing so-called "somatic" effects in patients—that is, effects that do not alter reproduc-

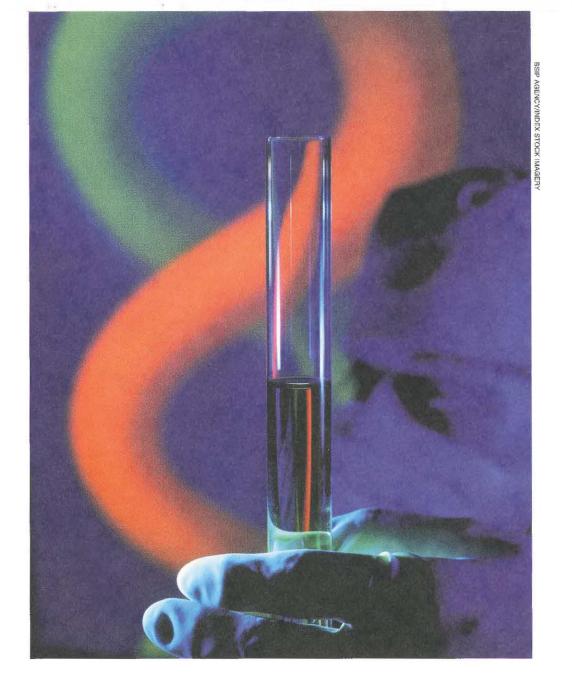
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ogy and gene transfer involving the actual manipulation of cellular DNA—will usher in a new era of genetic medicine.

Gene therapy already is a reality.

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1. See McLachlan, Ho, Davidson-Smith, Samways, Davidson, Stevenson, Carothers, Alton, Middleton, Smith, Kallmeyer, Michaelis, Seeber, Naujoks, Greening, Innes, Dorin, and Porteou, Laboratory and clinical studies in support of cystic fibrosis gene therapy using pCMV-CFTR-DOTAP, 3 GENE THER. 1113-1123 (1996); Colledge, Cystic fibrosis Gene Therapy, 4 CUR. OPIN. GENET. DEV. 466-471 (1994); McElvaney, Is gene therapy in cystic fibrosis a realistic expectation?, 2 CURR. OPIN. PULM. MED. 466-471 (1996).



tive cells and therefore that would not be passed on to the patient's offspring. But studies have been proposed in which genetic manipulations would change the DNA inside eggs or sperm.² These so-called "germ line gene therapies" introduce the possibility of eliminating genetically-related diseases in succeeding generations.

The future holds the prospect of even more daring genetic manipulations. The Human Genome Project will provide scientists with the data and tools to identify and understand the basis of genetic diseases and disorders, as well as other genetically-related traits. This creates the possibility of genetic interventions to enhance non-disease traits, for example, to increase strength, stamina, and perhaps even intelligence. Nor

are these enhancement technologies just in the realm of science fiction. Scientists have begun to use gene transfer technologies to enhance the immune systems of advanced cancer and HIV-infected patients, and they are experimentally transferring "foreign" genes (i.e., not one's own) into healthy subjects in search of new mechanisms to deliver gene therapies to patients.³

These new technologies will create a host of difficult, often unprecedented, ethical and legal controversies, many of which will find their way to the courts for resolution.

2. Cooke, Pushing the Human Limit: Gene Therapy That Could Affect Future Generations Too, Newsday, August 30, 1990, at A6.

^{3.} See Recombinant DNA Advisory Committee, Discussion Regarding the Use of Normal Subjects in Human Gene Transfer Clinical Trials, March 6-7, 1997, pg. 2 (in author's possession) (discussing protocol to characterize local, systemic and distant compartment immunity in normal individuals after intradermal administration of a replication deficient Ad5-based vector carrying gene coding for the E. coli enzyme, cytosine adenase).

Access issues

New gene therapies will prevent, cure, or more effectively treat many diseases that previously were unavoidable, incurable, or untreatable, or that responded to treatment only incompletely or was accompanied by numerous side effects. Gene therapy therefore will be in great demand. If it provides a cheaper alternative to existing medical interventions, it will be embraced by patients and readily offered by managed care plans and other third-party payers, such as Medicare and Medicaid. But in many cases, a gene therapy will increase rather than decrease health care costs. For example, it might be a more effective but also more expensive treatment than before. Or, it might target a disease for which there were no previous medical options, and thus no treatment cost. In these cases, third-party payers will resist paying for these new technologies, and this will lead to disputes that come before the courts.

In the case of private health insurance plans, the conflict will be over the scope of coverage. This is an issue with which courts are familiar, although not one that they necessarily have resolved consistently or with ease. It requires judges and juries to examine the language of the policy to see if the treatment in question-in this case, gene therapy-is explicitly excluded from coverage. Most likely, the treatment is not mentioned specifically in the policy (because of plan administrators' worries over the application of the expressio unius est exclusio alterius doctrine. which holds that when a list includes specific items, items not included are presumed to be excluded), and the insurer contends that the therapy is excluded under general policy language because it is not "medically necessary" or because it is "experimental."

The courts have wrestled with the meaning of these terms in cases involving other new medical interventions, such as bone marrow transplants for breast cancer.⁴ The outcomes in these cases are mixed, in

part because they depend on the language of specific health insurance policies in question, but also because some judges and juries are more sympathetic to patients and their families, while others are more concerned with the insurers' need to control their costs. Nor can the courts simply rely on whether or not the gene therapy has been approved by the Food and Drug Administration; although most gene therapies will require FDA approval before they may be marketed in interstate commerce, physicians lawfully may recommend to patients an approved therapy for a purpose for which it has not been approved.5

Increasingly aggressive efforts by managed care organizations to lower costs have given rise to one particular type of coverage decision that adversely affects an enrollee's chances of obtaining access to gene therapies: prospective utilization review. Under prospective utilization review, a health care provider must obtain the plan's agreement to cover a service before it is given to the patient; otherwise, the plan will not pay for the service even if in fact it would be covered under the plan. The process of challenging a plan's refusal to cover a service can be time-consuming, and all the while the patient is being denied access to the treatment. (In contrast, under the older, less aggressive form of management known as retrospective utilization review, the provider furnishes the service first and then submits a claim for reimbursement. If the plan determines that the service is not covered, the patient may be forced to pay the provider, but at least the patient has received the benefit of the treatment.)

Coverage disputes also arise under government entitlement programs such as Medicare and Medicaid. Medicare law, for example, excludes coverage of services that are "not medically necessary or appropriate." New gene therapies would not be considered medically necessary if they were still being investigated for safety and efficacy.⁶

Both private health insurance plans and public programs are establishing administrative grievance procedures for resolving coverage controversies. An increasing number of private plans are requiring enrollees to arbitrate these disputes, a practice that has provoked varying judicial responses.7 As state legislatures move to regulate managed care plans, they are enacting laws that mandate the adoption of grievance procedures for coverage disputes, often requiring that the disputes be resolved by external bodies.8 The federal government has established administrative procedures for grievances involving Medicare and Medicaid HMO's.9 The Patients Bill of Rights, although currently stalled in Congress, would create an elaborate administrative appeals procedure. Often, these administrative measures by their terms preclude judicial review.10 Over time, courts therefore may find themselves less involved in disputes over coverage.

5. Mehlman, How Will we Regulate Genetics, WAKE FOREST L. REV. (forthcoming)

^{4.} Nichols v. Trustmark Insurance Company, 1 F.Supp 2d 689 (Ohio, 1997) (treatment was not experimental or research even though it purported to be part of a protocol); Taylor and County of Marquette v. Blue Cross/Blue Shield of Michigan, 517 N.W. 2d 864 (Mich. App, 1994) (the terms experimental and research were found to be ambiguous and treatment was not experimental even though research was an underlying purpose); Bechtold v. Physicians Health Plan of Northern Indiana, Inc., 19 F.3d 311 (7th cir. 1994) (AMBT is not considered reasonable and necessary); Grethe v. Trustmark Insurance Company, 881 F.Supp 1160 (III, 1995) (denied treatment because it did not meet the definition of medical necessity because procedure was specifically part of a research protocol).

^{6.} See Health Care Financing Agency, US Department of Health and Human Services, Criteria and Procedures for Making Medical Service

Coverage Decisions that Relate to Health Care Technologies, 54 Fed. Reg. 4302 (1989) (proposed rule) (explaining that "necessary" means, inter alia, "safe, effective, non-investigational, and appropriate").

^{7.} Compare, e.g., Erickson v. Aetna Health Plans of California, 1999 Cal. App. LEXIS 347 (1999) (upholding binding arbitration) with George Washington Univ. v. Scott, 711 A.2d 1257 (D.C. Ct. App. 1998) (refusing to enforce arbitration clause)

^{8.} M.S.A. §62Q.30 (1998); Neb.Rev.St. §44-7307 (1998); 74 Okl.St.Ann. §1332 (1998); WV ST §33-25A-12 (1998).

^{9. 42} CFR §434.63(b) (1999); 42 CFR

^{§417.124(}g) (1999).

10. 28 PA Code §9.73 (1999) (final appeal of denial is conducted by a committee established by the board of directors of the health maintenance organization); AL Admin.Code 420-5-6..08(1998) (denial appealable only to the State Insurance agent).

Human experimentation

The adoption of a new medical technique typically is preceded by extensive scientific studies to establish its safety and efficacy. In the case of new gene therapies, these studies would be required by the FDA under its authority to regulate drugs and biologic products. Disputes may arise over the ethics of conducting these investigations, particularly on the appropriateness of experimenting on children and fetuses, and in the case of germ-line therapies, on human embryos (germ-line therapy involves altering DNA of early-stage embryos so that the alteration occurs in its repro-

ductive cells).11 Courts may be called on to resolve conflicts between the wishes of researchers, parents, and the subjects. For example, to what extent does a parent have the authority to enroll a child in a gene therapy experiment when there is no direct benefit to the child?

Courts also will be called upon to settle disputes over proprietary in-

terests in new therapies. Disputes between inventors and research sponsors may involve the application of traditional intellectual property doctrines to novel genetic technologies. More unusual controversies, involving both novel legal doctrines and novel technologies, are likely to arise between experimenters and their subjects, such as is illustrated by the approach taken by the California Supreme Court on the commercialization of cell lines in Moore v. Regents of the University of California (1991). In that case, the court held that researchers must inform patients of the commercial motivation behind their research, presumably to give patients a chance to negotiate an economic benefit for themselves.

Standard of care

New gene therapy technologies raise complex questions concerning the appropriate standard of care for health care professionals. Physicians who fail to recommend a new technology to their patients may run the risk of malpractice liability, even though the technology has not yet become incorporated into standard practice. The question remains open when awareness of a new technique has sufficiently diffused throughout the community of health professionals that the technique must be offered to patients as an alternative to more traditional therapies. On the

To what extent does a parent have the authority to enroll a child in a gene therapy experiment?

other hand, physicians who recommend a new technique before it becomes standard practice must be careful to disclose to patients that the technique is still experimental, and to obtain the patients' informed consent to employ an experimental approach.

These liability risks accompany all medical innovations. What may set gene therapy apart is the unprecedented potential that it may offer, for example, the ability to successfully combat genetic illnesses that were hitherto unresponsive to treatment. As a consequence, patients may demand access to gene therapy when they first hear about it, even though it is still in the early stages of testing, and they may seek to hold health professionals legally responsible for failing to provide them with the nascent treatment. This may embroil the courts in disputes similar to the celebrated but singular case of Helling v. Carey (1974), in which the court disregarded expert testimony

that providing patients with a new test for detecting glaucoma was not yet required by the ophthalmologist's standard of care.

The rapid pace of gene therapy development will impose liability risks particularly on two groups of health professionals: primary care physicians and genetic counselors. Primary care physicians are vulnerable because, compared with physicians who specialize in genetic medicine, they may not be as familiar with new gene therapies.12 Yet they will serve as the gateway to these therapies, particularly if managed care continues to require patients to obtain referrals

> to specialists from their primary care physicians before the plan will pay for specialty care. Patients who are harmed when inadequately informed primary care physicians fail to refer them to genetic counselors or gene therapy specialists may bring malpractice actions. If the patients suspect that the primary care physicians' failure to refer them is

motivated in part by the financial pressures exerted on the physicians by the patient's managed care plan, the patient may attempt to sue the physician for breach of fiduciary duty as well as for malpractice. Alternatively, the patient may sue the managed care plan, either under a theory of vicarious liability (if the physician appears to be employed by the plan) or corporate negligence. Moreover, courts increasingly are overlooking ERISA preemption problems and holding employer-sponsored health plans liable for substandard care.

Malpractice actions against genetic counselors may find their way to the courts as these health care professionals become more integrated into primary patient care in response to the development of new genetic tests and therapies. Genetic counselors, who typically are not physicians, often will serve as a layer of expertise between primary care physicians and physician geneticists. In this role, they will be responsible for educating

^{11.} See, e.g., Ethics Officials to Investigate Experi-ments on Children, New York Times, April 15,

^{12.} See Hoffman et al., Physicians' Knowledge of Genetics and Genetic Tests, 68 ACAD. MED. 625 (1993).

patients at risk for genetic ailments about the benefits and risks of new genetic technologies. Not only will they have to inform and advise patients about the complex matrix of individual genetic risk factors revealed by an expanding array of genetic tests, and to help patients compare the medical benefits and risks of various gene therapies and alternative treatments; they also will be the primary source of patient information about the non-medical costs of accessing genetic technologies, including the risks of insurance and employment discrimination.

Beyond gene therapy

As mentioned at the outset of this article, the revolution in human genetics will extend beyond identifying and preventing or treating genetic ailments. The same techniques that respond to genetic disorders also will be applicable to non-disease traits. Currently much work is underway to identify the proteins that genes "code for" in order to correct protein imbalances that produce illness. The same process can be used to produce drugs that affect any other protein-dependent characteristic, not just those that are regarded as illnesses. Similarly, gene transfer technology that will be used to remove errant DNA or to install healthy DNA also will be able to manipulate DNA for other purposes.

At this point it is not known how many non-disease human characteristics are, at least in part, inherited. But research already has confirmed that certain traits that many would consider fundamental to personal well-being and social success-traits such as beauty, strength, and intelligence—are substantially influenced by a person's genetic endowment.¹³ Many of these traits probably are "multifactorial"—that is, the result of the interaction of numerous individual genes and with environmental factors. Altering the function of one of these genes may have undesired effects on other physical or mental characteristics. Eventually, however, research is likely to reveal techniques for successfully "improving" or "en-



Research is likely to reveal techniques for successfully "improving" or "enhancing" non-genetic traits such as strength or beauty.

hancing" a person's non-disease genetic traits. This raises a host of problems that will begin to confront the judicial system in the next century. I want to discuss a few of the most challenging issues here.

Parental authority

It is a truism that parents typically want to give their children the best chance in life that they can. Indeed, some parents seem to know no bounds, such as the mother who was sentenced to 10 years in jail for plotting to murder a popular junior high school cheerleader so that her daughter could fill the vacancy on the cheerleading squad. 14

Parents not only put their children in private schools and pay for piano lessons; increasingly they turn to medical interventions to give their kids a perceived advantage over others. An endocrinologist reports being asked by parents to prescribe human growth hormone to their child so that she could gain the two inches in height needed to make her an irresistible candidate for college volleyball scholarships. ¹⁵ A recent report in the press says that a growing number of parents in California and other Sunbelt states are giving their daughters breast implants as high school graduation presents. ¹⁶

The question that the courts will be forced to struggle with is whether there is a legal limit to the authority of parents to manipulate the genetic characteristics of their children. One way this issue will arise is when parents give their children drugs to improve performance in sports competitions or mental achievement tests. Even if these practices are not expressly forbidden by law or by the private legal rules governing the activity, the possible health risks may subject parents to charges of child endangerment. Similar doubts about parental fitness would arise if parents agreed to let their children participate in experiments to determine the safety and efficacy of enhancement prod-

(demonstrating that elementary cognitive tasks display genetic effects).

9-A.

^{13.} See, e.g., Bouchard, Genes, Environment, and Personality, 264 Science 1700 (1994) (stating that "two-thirds of the reliable variance in measured personality traits is due to genetic influence"). See also Finkel et. al., Heritability of Cognitive Abilities in Adult Twins: Comparison of Minnesota and Swedish Data, 25 Behavior Genetics 421, 430 (1995) (estimating that cognition in early and middle adulthood has a heritability factor of approximately 81%); Petrill et. al., The Genetic and Environmental Variance Underlying Elementary Cognitive Tasks, 25 Behavior Genetics 199 (1995)

^{14.} See, Cheerleader Case Sentence, N.Y. Times, Sept. 10, 1996, at A23 ("[a] woman who offered her diamond earrings in a murder-for-hire plot aimed at getting her daughter on the junior high cheerleading squad was sentenced to 10 years in prison today").

^{15.} Personal communication from Thomas H. Murray, President, The Hastings Center. 16. Cleveland Plain Dealer, April 23, 1999, at

ucts. In none of these cases, moreover, would the parents be able to hide behind the shield of religious freedom, as they often can now in making questionable treatment decisions for their children.¹⁷

Yet parents are not likely to wait until a child is born in order to attempt to influence its genetic inheritance, including its inheritance of non-disease characteristics. The availability of genetic tests will open the door to several types of genetic enhancements that will take place much earlier. The first of these is preconception enhancement, in which decisions about whether or not and with

whom to conceive a child would be made on the basis of pre-conception genetic testing. Just as some people now test themselves to avoid conceiving a child with another person who is a "carrier" for a recessive genetic disorder, prospective mates in the future could test themselves to ascertain if they were likely to pro-

duce offspring who were "superior" in terms of non-disease characteristics. Unsatisfactory results would lead to decisions not to marry or not to conceive, at least not without employing genetic manipulations to improve the genetic profile of the offspring.

Another form of genetic enhancement stemming from genetic testing would be enhancement via selective abortion. Fetuses would be tested in utero and those that did not match up to parents' expectations would be aborted, just as fetuses currently might be aborted if they tested positive for abnormalities or incurable

diseases. An alternative to selective abortion would be *embryo selection for enhancement*, which combines genetic testing with in vitro fertilization so that embryos were tested before they were implanted in the womb, and only embryos with advantageous characteristics were implanted.

Finally, and most dramatically, an early-stage embryo might be genetically altered prior to implantation, with DNA inserted or deleted to produce desired traits in the resulting child. If performed at an early-enough stage of embryonic development, the alteration would affect all subsequent fetal cells, including

Those who can afford to purchase genetic enhancements will gain significant social advantages.

germ cells—that is, those that became eggs or sperm. This would result in *germ-cell enhancement*, in which genetic changes would be passed on when the enhanced individual reproduced.

Some of these actions undoubtedly lie within the realm of constitutionally protected personal autonomy and reproductive freedom, for example, the decision about whom to marry based on genetic testing. Other activities may not be so clearly protected. Some scholars argue, for example, that the state has a legitimate interest in regulating selective abortion and embryo selection when performed for enhancement pur-

poses, even though parents have a constitutional right to abort and perhaps even to select embryos for implantation when they do so for medical reasons, such as to avoid the birth of a child with a genetic illness.¹⁸

An interesting question is what the state's interest would be in regulating parental access to genetic enhancement for their children. The interest might be the need to prevent harm to the future child, similar to the justification offered for government actions to prohibit illegal drug use by pregnant women that threatens the health of the fetus. Yet assuming that genetic enhancement techniques are

developed that do not physically harm the child, the state would have to rely on less tangible forms of harm. Some commentators have suggested that genetic enhancement interferes with the child's right to genetic autonomy—that children deserve a genetic endowment free from parental manipulation. ¹⁹ Yet par-

ents invariably manipulate their children's futures once they are born. What is so different about doing so before the child is born, assuming that the manipulation is beneficial to the child?

A stronger basis for upholding governmental restrictions on parents' ability genetically to enhance their children might be the negative impact of genetic enhancement on our democratic political system. Genetic enhancement is likely to be accessible only to wealthier families, since it is not likely to be covered by public or private health insurance plans.²⁰

Assuming that genetic enhancement is effective at improving personal traits that correlate with social success, those who can afford to purchase genetic enhancements will gain significant social advantages, and the ability to genetically enhance their children, particularly the use of germ line enhancements that are passed on to succeeding generations, could create a "genobility" with an unassailable lock on power and privi-

^{17.} See, e.g., Massie, The Religion Clauses and Parental Health Care Decisionmaking for Children: Suggestions for a New Approach, 21 HASTINGS CONSTL. L. Q. 725 (1994).

^{18.} See, e.g., Malinowski, Coming Into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening, 45 HASTINGS L.J. 1435, 1450 (1994). Cited in Robertson, Genetic Selection of Offspring Characteristics, 76 B.U. L. Rev. 421 (1996).

^{19.} See generally Agar, Designing Babies: Morally Permissible Ways to Modify the Human Genome, 9 BIOETHICS 1-15 (1995); Elliot, Identity and the Ethics of Gene Therapy, 7 BIOETHICS 27-40 (1993); Kahn,

Genetic Harm: Bitten by the Body that Keeps You?, 5 BIOETHICS 289-309 (1991); Persoson, Genetic Therapy, Identity and the Person-Regarding Reasons, 9 BIOETHICS 18-31 (1995); Zohar, Prospects for "Gene Therapy"—Can a Person Benefit from Being Altered?, 5 BIOETHICS 275-288 (1991); Dwyer, Parents' Religion and Children's Welfare: Debunking the Doctrine of Parents' Rights, 82 CAL. L. REV. 1371, 1446-1447 (1994), Cited in Robertson, supra n. 18.

^{20.} For a fuller discussion of wealth-based access to genetic enhancement, see Mehlman and Botkin, Access to the Genome: The Challenge to Equality (Georgetown University Press, 1999).

lege. The threat that this poses is more than just a philosophical objection to social inequality; it is a threat to the fundamental belief in equality of opportunity that sustains our political system in the face of frank disparities of wealth, privilege, and power. If, as the result of wealthbased access to genetic enhancement, society becomes divided into genetic haves (the enhanced) and have nots (the unenhanced), the possibility of upward social mobility will be seen as illusory. In the face of such a hardened class structure, the underclass is likely to rebel, in turn provoking anti-democratic repression by the genetic upper class. Even if a stable political system eventually emerged, it would not resemble Western liberal democracy.

Avoiding such a fate is a sufficiently compelling state interest to justify a wide range of restrictions on parental enhancement of offspring, as well as substantial limitations on the freedom of adults to purchase enhancements for themselves. For example, the law might legitimately ban the use of germ line genetic enhancements, and it might allow persons to purchase somatic enhancements for themselves only on condition that they make an enforceable commitment to employ their advantages for social and not just personal benefit, in much the same way that we license professionals such as doctors and lawyers.21

Unfairness

No matter what approach society takes to genetic enhancements, some individuals undoubtedly will obtain them—whether by becoming licensed or by purchasing them in an unregulated free market or through black or gray markets in a highly restricted system of access. These individuals will gain significant advantages over unenhanced persons with whom they interact or compete. How should the law respond to the potential unfairness of these interactions?

The law is no stranger to imbalances between interacting parties. In certain situations, courts are called upon to enforce bans on such interac-

tions, such as the private rules that prohibit the use of performance-enhancing drugs in the Olympics or other sports competitions, or the securities laws that ban trading on inside information. In other situations, the law requires the advantaged party to disgorge the advantage to the benefit of the other party, such as by requiring disclosure of information to correct a material mistake by the other party to a contract negotiation.²² The doctrine of unconscionability allows courts to void a contract if the outcome, resulting from an imbalance of market power or information between the parties, seems too unfair.²³ In still other contexts, the law eliminates the arm's length nature of the transaction, making the advantaged party a fiduciary who must act in the other party's best interests.24 Yet in some instances, the rules seem blind to the potential unfairness. SAT scores for college applicants are not weighted in terms of IQ, despite the obvious unfairness. Shorter basketball players are not allowed to shoot from stepladders.

These varying responses of the law make it difficult to predict how courts will respond to the unfairness created by genetic enhancements. Yet it seems certain that, at least in some cases, courts will feel compelled to level the playing field.

Negligence

A final illustration of the potential impact of genetic enhancement on the courts is its effect on the standard of care to which people are expected to adhere when they create risks of injury to one another. Should an enhanced person be held to the standard of care of an ordinary reasonable person, or to the standard of an enhanced person? An obvious answer might be that, if enhanced persons ought to be better at avoiding accidents than unenhanced persons, then the enhanced persons should be held to an enhanced person's standard of care. In other words, they should not escape liability by showing that they met a reasonable person's standard of care when, by virtue of their enhancements, they ought to

have done better.

Automobile drivers with enhanced vision who run over children, for example, should not be heard to argue that, although they could have seen the child in enough time to stop, they were not negligent since an ordinary person would not have been able to stop in time. This seems to be the answer that the Restatement of Torts would give, since section 289 states that, at least in regard to appreciating the risk created by one's behavior, an actor must use "such superior attention, perception, memory, knowledge, intelligence, and judgment as the actor himself has."

A good argument can be made, however, that when it comes to reducing the costs of accidents, we indeed ought to hold an enhanced person to the lower standard of an ordinary "reasonable" person. The reason is that by not penalizing them with an enhanced person's standard, we will encourage more people to enhance themselves, thereby reducing accidents simply because, as a result of their better vision or reflexes or intelligence, enhanced people are better at avoiding them.

A different society

The broad scope of the issues mentioned in this article-from automobile accidents to altering the genes of future generations—demonstrates the breadth of the impact that gene therapy and related technologies will have on our society. They will challenge conventional notions of illness, insurance, personal worth, and desert, and the limits of governmental control over individual freedom and parental discretion. Ultimately the courts will decide how far the law can go in response to these challenges. One thing is certain: the society that emerges will look very different from our own. 414

22. See Restatement (second) of Contracts \$161(d) (1981).

^{21.} For a more complete discussion of these societal responses, see Mchlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, IOWA L. REV. (forthcoming).

^{23.} See Restatement (second) of Contracts §153 (1981).

^{24.} See Restatement (second) of Trusts §170 (1957).



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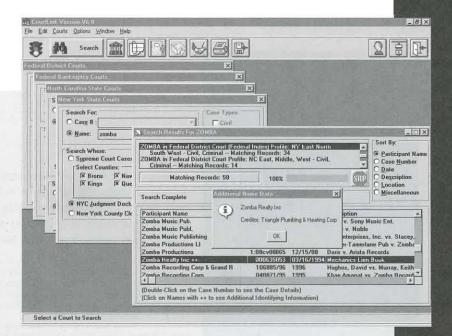
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HOPE FEAR AND GENETICS Judicial responses to biotechnology

Although still in its infancy, biotechnology has already introduced such controversial issues as DNA typing, reproductive technologies, and patenting of animals before courts and tribunals worldwide.

by E. Richard Gold



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hose of us who write, read, or talk about genetics and biotechnology inevitably encounter a barrage of legal principles under various guises

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that seem to suggest ways that the legal system ought to deal with advances in genetics. We must worry, we are told, about such things as biodiversity, the Precautionary Principle, the Principle of Future Generations, the Prevention Principle, the

Common Heritage of Mankind, economic analysis, equal rights, privacy, and rights to information. Not only do we not really know what these things are—and, from the look of

I would like to thank Erin Rogozinski for her truly helpful research and editing assistance, the Law Foundation of Ontario for its financial assistance, and Tory Tory DesLauriers & Binnington

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1. The term genetics refers to the study of animal and plant genes and the links between genes and certain characteristics and diseases. The term biotechnology refers to any techniques using living organisms to make products, improve plants or animals, or develop micro-organisms. U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology. Ownership of Human Tissues and Cells—Special Report 24 (Washington, D.C.: U.S. Congress, Office of Technology Assessment, 1987).

things, neither do those who propose them—but their application to genetics is neither obvious nor easy.

Some things about genetics, however, are fairly clear. First, the field raises issues that are important to the economy and job market, but also to religious beliefs, family, community, health, the environment, and international relations. These are not simple areas, nor are they easily confined.

Second, the genetic revolution through which we are living promises to be as profound as any technology-based revolution, from the advent of the printing press, to the invention of the assembly line, to the personal computer. Like these previous revolutions, the genetic revolution will likely alter the way we carry on in business and in our personal lives.

Third, this genetic revolution is unidirectional; in other words, the consequences of increased genetic knowledge and technology are irreversible. Thus, once we permit an activity to go forward, such as introducing a genetically altered plant or animal into the environment, we do so in perpetuity.

Fourth, the genetic revolution, to play on the well-known slogan, will bring good things to life, literally.

Through genetic manipulation, we can hope for more nutritious and flavorful foods that are easier to grow. We can also look forward to new techniques to prevent and treat disease and increased knowledge—and thus control—over our individual health. Of course, badly or recklessly done, genetics can reduce our health and seriously endanger the environment. It all depends on the choices that we, as a society (in the largest sense, including our neighbors around the globe), make.

Given the profound effects that will likely arise from genetic research, it is far from surprising that we have created the multitude of principles listed at the beginning of Although still in its infancy, biotechnology has already introduced before courts and tribunals worldwide such controversial issues as DNA typing, reproductive technologies, and patenting of animals. As the impact of biotechnology grows, the judiciary will increasingly be required to address genetics-related issues.

The purpose of this article is to bring some clarity to the maze of principles touching on genetics, and to present a simplified approach to making decisions in the era of genetics. It first examines the particular problems posed by genetics for the legal system. Then, it describes four approaches that a judge could take to evaluate a dispute involving genetics and suggests ways to handle the problems posed to the legal system.

The genetics difference

The introduction outlined some of the defining characteristics of genetics. These included its potential to substantially increase human welfare through the discovery of new medical therapies, through the prevention of existing diseases, and through the introduction of more nutritious and easier to grow food. But they also included the great threats that biotechnology poses to the environment and human health, many of which could cause irreversible harm.

These are three additional features that make this field different from other technologies: the inhibiting effects of patent protection (sometimes called the tragedy of the anticommons); the impact of genetics on health policy; and the ethical and religious questions posed by genetics and genetic technologies (genetic technologies or biotechnology is based on genes and genetic information, genetics is the general field).

Tragedy of the anticommons. The first problem is one raised directly in academic literature² but also indirectly through court decisions.³ It involves the somewhat counter-intuitive notion that private property

rights can impede, rather than encourage, innovation. This concern arises because of the way genetic information wields its effect on biological systems. Each cell within every human, animal, and plant contains long strings of code made up of the chemical DNA. These codes are called genes, and carry instructions for making proteins. Each protein interacts with other proteins, resulting in activity (life) within a cell. Each cell within an organism interacts with others to create the organism.

Granting private property rights to minute parts of this layered and interconnected system creates the potential for the tragedy of the anticommons. Consider the following example. Imagine trying to identify all the codes that go into a seemingly simple process like digesting sugar. There will be a multitude of cells involved in this process containing different sets of proteins, each specified by a different gene, each of which contains different codes. Thus, the number of codes required to carry out this simple procedure is extremely large.

Imagine now that different people have the exclusive right to use a particular series of these codes (such as the series that defines a gene). This means that researchers wanting to use, copy, or study (at least in a commercial context) these series of codes can only do so after gaining (usually for a fee) approval from the rights holder. Anyone wishing to study the genetic basis for digesting sugar will thus have to buy rights from a very large number of people—so large a number, in fact, that he or she will simply give up and study something else.

Thus emerges the tragedy of the anticommons: we may so split up rights to use genetic information that it will become prohibitively expensive for anyone to conduct meaningful research. So while our patent system was designed to promote research through the granting of property rights (to prevent a tragedy of the commons in which no one would invest in research without having private property rights), its effect on the

this article. But acknowledging the existence of these principles, and even their relevance, does not tell us how or when to apply them.

^{2.} Heller and Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698-701 (1998).

^{3.} E.g., Moore v. Regents of the University of California, 447 U.S. 303 (1980).

ownership of genetic information may actually be to stifle research.⁴

This situation is particularly acute with respect to upstream research that involves the basic building blocks of our genetic knowledge. Virtually all research into the biochemistry of the body will require access to these data. If the data are protected by patents, researchers will have to spend a significant amount of time and money purchasing rights to their use. To make matters worse, basic research is the most speculative and the least likely to directly result in any profit to offset this expense. This problem does not present itself to nearly the same extent with respect to patent rights over downstream products, such as a specific medication to treat a particular disease, because many paths exist to treat that disease, most of which will not require access to one specific medication.

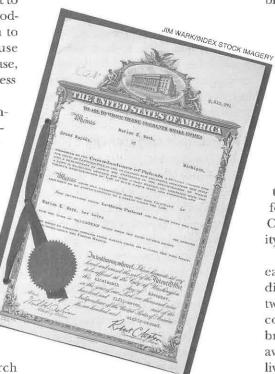
Given that genetics largely involves upstream knowledge—genes and other DNA sequences—the traditional ways in which we have provided incentives to conduct scientific research and encourage the development of new products, through the grant of exclusive rights in the form of patents, will likely not work. This presents a fundamental challenge to the ways in which the legal system interacts with genetics.

Health policy. Two principal applications of genetic research occur in the fields of health and agriculture. This section concentrates on the former (although it is worth noting that, as the dispute over genetically modified foods all too well illustrates, even agricultural uses of genetic technology have health policy implications).

Through our understanding of the genes in our bodies, we can hope to develop new therapies to treat or prevent disease. The trick is to encourage the development and implementation of methods for both the treatment and the prevention of disease in a balanced manner. Historically, we have improved lifespan and quality of life more effectively and efficiently through public health measures (education, clean water, sanitation services, etc.) than through treatment.⁵

Unfortunately, we rely on market forces to achieve this balance through the granting of property (patent) rights in genetics research, and because of this reliance such a balance will not likely be achieved. Reasons include the fact that the purchase of health care services does not really occur in an open market: patients rely almost exclusively on phy-

sicians for information about what



services to purchase from that very physician; health insurance rules, and not patient bargaining, often determine treatment options; and patients often are in too much pain to make decisions about which health services to purchase.⁶

While these shortcomings provide reason enough to eliminate a primary role for the market in setting the balance between prevention and treatment—in other words, in establishing our health policy—there are other reasons that market forces fail to reach this goal. Consider the example of the controversial breast cancer

gene screening tests. Myriad Genetics, Inc. currently offers, through an affiliate, a genetic screening test for women concerned that they may have a genetic predisposition to a rare inherited form of breast and ovarian cancer. Women in general have a one in eight chance of contracting breast cancer in their lifetimes; for women carrying a mutation in one of two identified genes, this risk jumps to as high as seven or eight in ten.7 However, the overall risk for a woman in the general population of carrying one of these mutations is very low: approximately one in 400.8 This is because fewer than seven percent of breast cancer cases are linked to one

of these mutations.9

Myriad and the Cancer Rescarch Campaign, through the Haddow Institute in England, both claimed to have discovered the second of the two breast-cancer-associated genes, BRCA2. Myriad is, and continues to be, a for-profit biotechnology company that is in the business of providing breast cancer genetic screening tests. The Haddow Institute is a not-for-profit research centre while the Cancer Research Campaign is a charity that aims to climinate cancer.

It is interesting to observe what each group hoped to do with their discovery of the BRCA2 gene. The two groups certainly had much in common: both wanted to make a breast cancer gene screening test available to help women plan their lives. The test offers women who are found to carry a mutation a chance

^{4.} Heller and Eisenberg, supra n. 2.

^{5.} Halm and Gelijus, An Introduction to the Changing Economics of Technological Innovation in Medicine, in Gelijus and Halm, eds, The Changing Economics of Medical Technology 1-20 (Washington: National Academy Press, 1991).

^{6.} Gold, Body Parts: Property Rights and the Ownership of Human Biological Materials 33 (Washington, D.C.: Georgetown University Press, 1996)

^{7.} Myriad Genetics, Inc., Terms of Payment and Reimbursement (visited August 11, 1999) https://www.myriad.com/gtpatb20.html.

Myriad Genetics, Inc., Questions and Answers About BRAC Analysis (visited August 11, 1999) http://www.myriad.com/gtpatb21.html.

8. Interview with Dr. Michael Stratton of the

Haddow Institute, U.K. (December 12, 1998).
9. Myriad Genetic Laboratories, Inc., Genetic Analysis for Risk of Breast and Ovarian Cancer 2 (1997).

to take (somewhat controversial) preventive steps against breast and ovarian cancer. It also allays the fears of those women who do not have the mutation but thought that they were at risk because of family history.

Apart from this overall agreement, however, the approaches taken by the two organizations were different. Scientists at the Haddow Institute feared that if the test became routine it could actually do more harm than good. For the vast majority of women, the negative test results would not only be useless but might, in fact, be misleading. Unless careful genetic counselling is given (and it rarely is),10 women may wrongfully believe that a negative test for a mutation means that they will never get breast cancer. In fact, their chance of getting breast cancer remains at one in eight. Therefore, these women should still take steps (diet, exercise, examinations, etc.) to reduce their risk of developing breast cancer or to detect it at an early stage. Because of this concern, the Cancer Research Campaign attempted to require its licensees to ensure that genetic counselling be offered, that only women with a family history of breast cancer would be given the test, and that there would be no advertising of the test.11

Myriad, on the other hand, does not impose any restrictions on those

taking the tests. To be fair, Myriad does recommend the test for women with a family history of breast or ovarian cancer and that they seek genetic counselling in conjunction with taking the test. But neither a positive family history nor counseling is required. Despite their recommendations, Myriad spends a significant amount on advertising the test and encourages investors to believe that the breast-cancer gene screening test will become "routine," opening up a U.S. market of \$150-200 million per year.12 Such revenues could only be achieved if the test were given to a far greater number of women than would be justified on medical grounds.13

This example illustrates that market forces are likely to lead to inefficient health policy that not only costs more, but actually diminishes health. Myriad did nothing wrong; they were, after all, only pursuing a profit in a perfectly legal and ethical manner. The conclusion is more insidious: corporations operating within acceptable business parameters are, given the market failure affecting health care, likely to be an inefficient way of creating good health policy. Blind trust in the market is, therefore, not only unwise: it is dangerous.

Ethical and religious values. The market is no better at protecting ethical and religious values than it is at ensuring health. Genetic research, testing, and products interact with a complex web of societal, community, and religious values on two distinct levels. First, the products can dramatically alter our lives, for both good and bad. Genetic techniques can identify individuals at risk for certain illnesses; sometimes this information can be used to prevent an illness, but it can also be used to exclude an individual from insurance coverage. We can use knowledge of the links between genes, the environment, and disease to clean up the environment to make it safe for all or we can impose the cost of avoiding environmental hazards only on those possessing the suspect gene.

The products of genetic engineering can help us preserve the environ-

ment, but newly introduced strains may kill and displace native species. In the future, artificial chromosomes¹⁴ carrying genes for selected traits can help cure genetic disease or be used to introduce a form of eugenics through the creation of a new human "superspecies" incapable of producing offspring with the rest of humanity. A second level of interaction between genetics and societal, community, and religious values arises from a concern that the genes of our shared humanity should not be treated as a commodity by researchers or biotechnology companies.

There is simply no room in this article to begin defining all the other ways that the results of genetic research challenge societal values. But, as the examples outlined above illustrate, a moment's reflection will confirm that the importance of human genes extends far beyond the economic incentive that is the subject matter of patent law.

We have not yet developed a mechanism within the law in which to consider and balance such societal concerns. Given the complex interaction of values, most of which are difficult to translate into a market price (exactly how much is privacy or good health worth?), reliance on the market is unlikely to yield an acceptable balance. While the market may be good at choosing the best paper clip, it is not a good way to choose the best ethics.

Judicial responses

Given the impact that genetics will likely have on many aspects of life, it will not be long before judges confront issues involving genetics on a regular basis within their courts. Obviously, there is some benefit in thinking through how, in general, courts should approach these issues before the tidal wave of genetics-related litigation hits.

The goal of the judge is to find the appropriate balance between further advances in biotechnology and protecting the environment and human health. Judges must decide in the reality of the moment and not simply in pursuit of some far off goal. And the

Giardello et al., The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis, 336 New Eng. J. Med. 823-827 (1997).

^{11.} Stratton, supra n. 8. Although this clearly was the intention of the scientists involved, the actual contract with the Cancer Research Campaign's licensee was less stringent. Interview with Guy Heathers of the Cancer Research Campaign Technology, U.K. (August 9, 1999).

^{12.} Myriad Genetics, Inc., SEC Form 10-K at 25 (September 24, 1998); Myriad Genetics Inc., SEC S-3 Registration Statement no 333-16143 at 5 (November 14, 1996); Stone and Schmidt, Myriad Genetics (\$15), 7 BIOTECHNOLOGY Q. 112 (1998); Myriad Genetics, Inc., AMA Introduces New Physician Guide on Myriad Genetics Breast Cancer Test-Increased Testing Likely as Patient Inquiries Swell (last modified June 2, 1999) http://biz.yahoo.com/prnews/990602/ut_myriad_1.html

^{13.} Michael Stratton estimates that the U.S. market for the screening test, if it were only administered to those truly at risk, would be approximately \$5 million. Stratton, *supra* n. 8.

^{14.} Highfield, Researchers Construct Chromosome, The London Telegraph (April 2, 1997) https://www.telegraph.co.uk:80/et?ac=000647321007942&rtmo=gZNnfNru&atmo=lllllllx&pg=/et/97/4/2/nchr02.html>.

reality is that biotechnology is advancing quickly, and not only in terms of scientific knowledge. Biotechnology is big business and will become even bigger. The biotechnology industry-which includes the business aspects of genetics—hires a large number of highly skilled employees, paying salaries that match. In addition, the genetic revolution will change the ways other industries do business, most notably insurance (more accurate assessments of risk), health care (more targeted therapies), security (better identification techniques), and agriculture (more profitable seeds or less costly pesticides). Government too will not be immune, as genetics provides an opportunity (or a risk) of easy identification whether in the criminal or social benefits context.

Given this reality, what is the mindset that a judge might bring to both the positive potential of biotechnology and to the fears that biotechnology engenders? Specifically, to what extent ought a judge to accept either the predictions of better health made by the biotechnology industry or the forecasts of disaster put forward by those opposed to biotechnology? And second, is a judge wise to rely on law to adequately deal with the dangers posed by biotechnology?

Four basic approaches are available to judges. Since no formal terms exist for these approaches, I have chosen my own: the Old Woman Who Swallowed a Fly, the Evolutionary, the Luddite, and the Euroskeptic. The reasons for these names will, I hope, become obvious from the description of each below. Each approach is based on a different attitude to two things. First is the attitude towards the effects of genetics itself: wildly enthusiastic, very pessimistic, or somewhere in between. Second is the judge's view of law and, in particular, of law's ability (or lack of ability) to adapt itself to quickly changing circumstances.

The Old Woman Who Swallowed a Fly. The first approach is based on having great faith in technology. Someone adopting this approach believes that biotechnology, and ge-

netic research in general, is an unmitigated good. They also believe, like the old woman in the children's song (the old woman ate a spider to kill the fly, then ate a bird to kill the spider, etc. until she ate a horse and died) that any problems that arise can be remedied. We can safely entrust our own and our children's safety, health, and environment to science, industry, and the market. One example of this approach is found in the United States Supreme decision Diamond Court Chakrabarty (1980). The Court was asked to decide whether to extend patent law to cover living organisms, in this case, an artificially created bacterium. Those opposed to the patent pointed to the potentially strong and negative health and environmental consequences of the research and suggested that the Court leave the issue to Congress. In a strongly written opinion, the majority extended patent coverage to the bacterium, extolling, as it did so, the economic virtues of technology and putting aside the claimed harms to the environment and human health.

Unfortunately, history does not support this beatific vision of technology. In fact, the introduction of technology often brings with it unintended and unwanted consequences. Nuclear energy, which promised clean and inexpensive energy in the 1960s, has brought with it not only nuclear accidents at Three Mile Island and Chernobyl, but also the still unsolved problem of long-term storage of nuclear wastes. Shoe-fitting fluoroscopes, used up to the late 1940s, took x-rays of children's feet to ensure proper fit of shoes; only later did the dangers of having exposed children to x-rays become apparent.

Neither can technology be relied upon to correct the problems that it creates. Consider the following example from Australia. The South American cane toad was introduced into Queensland in 1935 to control two cane beetle species that were damaging the local sugar cane harvest. Unfortunately, not only did the toads fail to control the beetles, but the cane toads themselves became a significant pest. Now, researchers are looking into viruses or fungi that can be used to control the cane toads. The effect these new agents may have on the environment is hard to predict.

Similarly, the introduction of wild European rabbits into Australia and New Zealand in 1859, and the introduction of the purple loosestrife in eastern North America in the early 1800s have led to environmental and livestock problems that have yet to be remedied. Like the old woman in the song, it is not wise to blindly depend on being able to correct our past wrongs.

The Old Woman Who Swallowed a Fly would leave decisions about the use of genetic information and the direction of genetic research to a combination of patent law and the market. As previously discussed, this combination is not only unlikely to efficiently encourage genetic research, but will probably undermine the development of a rational and ethical health policy. It also, unfortunately, completely fails to even consider environmental, religious, and community concerns relating to genetic information and genetic research.

The Evolutionary. The second approach also involves faith in science, but not of an unmitigated and blind nature. But some of that faith is transferred into a different kind of faith: a belief that the legal system is able to prevent harm before that harm gets out of control. Essentially, this is the view that what science cannot solve, the legal system will.

This is a traditional approach within the law; the only difference is that it is applied to biotechnology. Judges espousing this view argue that the legal system is flexible enough to deal with genetics. In particular, they point to patent law, which adapted itself over the last century to an amazingly large variety of technologies, from machines, to chemicals, to software systems. According to this approach, to the extent that problems do arise, judges will modify the old rules to fit the circumstances before them.

One example of this approach is the majority decision of the California Supreme Court in Moore v. Regents of the University of California (1990). That case involved a claim by a patient that his physician had used the patient's removed tissues in highly lucrative research. The majority of the court refused to accept the patient's contention that, to protect autonomy, patients must have a property right in their own tissues; instead, the majority modified the law of informed consent to require physicians to reveal any commercial interest they might have in the medical procedure. The result is

that, while leaving science to do its work uninterrupted, the court was able to address an apparently narrow concern—albeit imperfectly—on an ad hoc basis.

The essential belief of the Evolutionary is that the legal system can respond to any harm threatened by a new technology before that harm becomes severe. We can allow science to move the economy and our lifestyles forward, safe in the knowledge that judges will respond when and if the need arises.

Although good in principle, the Evolutionary misses one critical point: biotechnological advances move far more quickly than the legal system. While judges were successful in modifying patent law to suit many different types of innovation, they had a long period of time to do so. This is unlikely to be true with respect to biotechnology. For example, the Human Genome Project-an international effort to identify and decode every human gene-originally anticipated to yield results in 2005, will be completed in 2003 or sooner, years ahead of schedule. One of the

Biotechnological advances applied to the environment are also one-way: once we have introduced a new organism, it cannot easily be removed. The Australian cane toad experience illustrates this potential problem. If we are too hasty, we risk introducing a genetically modified organism into the environment before we learn if it could cause serious harm.

Biotechnological advances applied to the environment are one-way: once we have introduced a new organism, it cannot easily be removed.

Given the fast pace of biotechnological change, the Evolutionist will find him or herself trying to evolve faster than the legal system can support. Cases take time to move through the judicial system. Precedents evolve slowly. In fact, this slow pace of change is one of the inherent limits on judicial power. Unfortunately, in the case of biotechnology, it threatens to undermine any coherent formulation of judicial policy.

The Evolutionary, like the Old Woman Who Swallowed a Fly, relies too heavily on existing patent law and market forces. As discussed throughout this article, these mechanisms are inadequate to the task of both encouraging innovation and achieving health policy. It is an insufficient response to say that the judiciary will make ad hoc changes as conditions change because these changes will

often not only be irreversible but very harmful and widespread. The Evolutionary also fails to provide a voice to the societal, religious, and community values attaching to genetics research. Not only will those concerned about these values feel left out but, as the following discussion points out, they may actually take aggressive action to prevent the use of genetic research in even those areas where it would be of benefit to health and the environment.

The Luddite. One need not, of course, take a positive view of biotechnology or any other technology. Instead of having faith that technol-

ogy will improve the economy and provide us with better health and better food, one could easily, as did the Luddites—the 19th century workers opposed to new technology-believe the oppo-This fear site. technology is fuelled by the seemingly ever-increasing news reports of technology gone wrong. Experiences with Mad Cow Disease (Bovine Spongiform Encephalitis), Belgian dioxin, and defective Coca Cola have

fueled this fear and made many distrustful of technology.

One consequence is that the public exerts pressure on the government to restrict use of new technology. The European reaction to genetically modified foods is a case in point. Following the Belgian dioxin scare and news that genetically altered corn was killing monarch butterfly caterpillars, 15 European consumers pressured both supermarkets and government to restrict the use of what they called "Frankenstein food." This resulted in an effective moratorium on the approval of genetically modified foods in Europe.

To what degree these fears of technology, and genetic technology in particular, are founded is unclear. To date, there are no scientific studies that definitely demonstrate either the safety or dangers of genetically

reasons for this speed is the commercial potential of these genes. Researchers will be rushing to patent them and put them into commerce before we have seriously considered the health policy and ethical implications of that patenting.

Yoon, Altered Corn May Imperil Butterfly, Researchers Say, N.Y. Times, May 20, 1999, at A-1.
 Burros, US Plans Long-Term Studies on Safety

Burros, US Plans Long-Term Studies on Safety of Genetically Altered Foods, N.Y. Times, July 14, 1999, at A-18.

modified foods.17

The Luddite fears technology and distrusts the law's ability to contain the harm caused by technology. Given that neither science nor the legal system have proved themselves able to prevent the harm that has resulted from Chernobyl, Mad Cow disease, or Belgian dioxin, this fear is far from unreasonable. Nevertheless, having a reasonable basis for concern does not amount to a justification for paralysis. Biotechnology is, whether anyone likes it or not, a reality. The real question is how to control it so that it is most likely to benefit us. It is too late to argue that we should abandon the enterprise.

The Euroskeptic. The fourth approach a judge could take to genetic information and genetic technology is to recognize the substantial benefits and the real threat of harm from this technology and the limited ability of the legal system to control that harm. The Euroskeptic takes a middle course of allowing technology to proceed, but slowly and under a watchful gaze.

This cautious approach is similar to that taken by the United Kingdom with respect to its involvement in the European Union and, in particular, with respect to the new European currency, the Euro. While all other major European states have adopted the Euro as their currency, the United Kingdom has retained the Pound and has vowed to only join "Euroland" after it has had a chance to measure the success of the Euro. This decision to "go slow" was made despite the fact that London's financial community has been one of the biggest advocates of introducing the Euro. Proceed, yes, but with caution.

While the Euroskeptic has deep reservations about genetic technology, he or she does not deny its potential benefits. But the Euroskeptic also believes that, once the technology is introduced to the market, its effects on environment and health are irreversible. Thus, a slow, cautious approach is most appropriate.

The Euroskeptic would not rely on patent law and the market to achieve the goals of encouraging research,

attaining a desirable health policy, and furthering other societal, community, and religious values. Rather, the Euroskeptic would carefully limit the impact of patent law and the market on genetic technologies and genetic research until the potential effects of these areas were carefully examined. The Euroskeptic would think twice before accepting that basic genetic knowledge is patentable or, if patentable, that the patent holder should have a wide monopoly. Similarly, someone taking this approach would encourage an open discussion to determine how this research and its products are to be used. This does not mean capitulating to the lowest common denominator, nor to the loudest opponent of genetic research; rather, it means trying to include a diversity of voices so that, through a wider consensus, we encourage more research with the full support of the public. Moving carefully does not mean abandoning the market or legal rules: it means viewing broad legal and democratic principles with a healthy dose of skepticism about claims of what the market can achieve on its own.

In summary, while accepting the basis for the fears of the Luddite, the Euroskeptic does not believe that an outright ban on genetic technology is called for. While agreeing with the Old Woman Who Swallowed a Fly that technology has much to bring us, the Euroskeptic does not believe that technology is an unmitigated good that can be trusted to cure its own ills. To this extent, the Euroskeptic and the Evolutionary agree.

The Euroskeptic differs with the Evolutionary, however, with respect to the legal system's ability to contain the harms of genetic technology. Unlike the Evolutionary, the Euroskeptic does not believe that we can fix all problems after the fact. Examples provided in this article illustrate how the law has been demonstrably weak in protecting us from this kind of harm.

The Euroskeptic will not allow the financial community, whether in relation to the Euro or to biotechnology, to decide for the rest of us whether and when to proceed. The Euroskeptic will not take steps that, like the abandon of the Court in Chakrabarty, place ultimate decision-making over our health and environment in the hands of industry actors whose goals are profit-maximization and not ethics maximization. Instead, the Euroskeptic will find methods to determine the future of genetic research that incorporate the many views about it.

Exercising caution

The Euroskeptic fits well into legal precedent. The approach of moving forward, but with caution, is the basis of the Principles of Precaution and Prevention. The latter states that we ought to limit the known harms that result from an action; the former says that we should presume that the introduction of a technology will have unanticipated and unwanted consequences. In exercising caution, we must not only ensure our own safety, but that of future generations. And this concept of safety should not be limited to physical safety: it also includes the right to be left alone (privacy), to not be discriminated against, and the right to know the basis for government action based on our genes.

Nevertheless, caution does not mean standing still. Biotechnology not only offers improved health and food, but economic growth. We can only move forward to protect health and the environment if we do so in a way that ensures the prosperity of the country. After all, poor countries cannot afford to be more cautious.

Judges will play an important role in the legal system's response to genetic research. As argued earlier, the judiciary cannot hope to curb, after the fact, the harms caused by this research and its applications. Judges must act pro-actively to establish standards that include doubt, both about technology and the legal system's ability to change in time.

^{17.} Greenberg, The Right to Know What We Eat, The Washington Post, July 7, 1999, at A-19.

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Saturday, March 4, 2000

9:00-10:30 a.m. Politics and Policymaking

Moderator: Professor Anthony Champagne, University of Texas at Dallas Featuring: Sheila Kaplan, Producer of Frontline documentary, "Justice for Sale" Professor Dawn Clark Netsch, Northwestern University School of Law

10:45-12:00 p.m. Coalition Building

Moderator: Seth Andersen, Director, Elmo B. Hunter Citizens Center for Judicial Selection Featuring: Edward W. Madeira, Jr., Chair, ABA Commission on Judicial Selection Standards

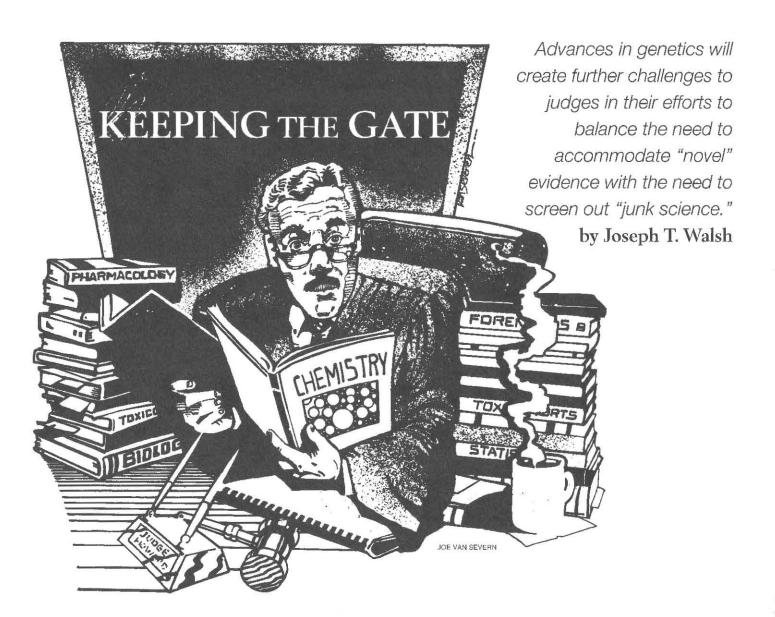
1:00-2:00 p.m. Discussion Groups

2:15-4:00 p.m. Future Reforms

Moderator: Professor Arthur Miller, Harvard University Law School Featuring: Professor Roy Schotland, Georgetown University Law Center

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The evolving role of the judiciary in admitting scientific evidence

he 1993 decision of the United States Supreme Court in Daubert v. Merrill Dow Pharm., Inc., was viewed as a watershed event. In abolishing the 70 year old Frye test for

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evaluating scientific evidence, the Court established a new, and somewhat controversial, standard. Under *Frye*, trial courts were simply required to determine whether the expert's methodology was generally accepted in the relevant scientific community. *Daubert* introduced a more elaborate, open-ended approach keyed to validating the reliability and relevance of

the methods employed by the expert. The new standard placed increased responsibility on the trial judge who was assigned a gatekeeper's role.

Daubert's teaching has since been refined and expanded both at the Supreme Court level and among federal and state courts who have sought to implement it. This article addresses post-Daubert developments and discusses the questions it, and its progeny, leave unanswered.

Despite its longevity, the *Frye* rule of general acceptance in the relevant scientific community was not without

^{1.509} U.S. 579 (1993).

its critics. Although adopted in pure or modified form in most jurisdictions, federal and state, the Frye standard posed a significant ambiguity: what is the relevant scientific community and who defines it? The Frye approach came under greater scrutiny over time. Courts wrestled with its application in technical areas lacking clear scientific underpinnings (such as psychological syndromes and voice printing). Perhaps the greatest barrier to Frye's continued viability, however, arose with the emergence of the Federal Rules of Evidence which, in turn, became the model for evidentiary standards in many state courts.

Rule 702 of the Federal Rules of Evidence, with its emphasis on the reliability of the expert, appears almost at cross-purposes to Frye's focus on the subject matter of the expert's opinion. Similarly, Rule 703, which permits an expert to use data not necessarily admissible in evidence in formulating an opinion provided such data is "of a type" reasonably relied upon by experts "in the particular field," seems to suggest a Frye-like test without the general acceptance requirement.

Courts seeking to reconcile Frye's general acceptance test with the more specific criteria imparted by Rules 702 and 703 struggled to provide a consistent practical guide for practitioners. To the extent that Frye was viewed as unduly conservative, courts sought to relax its application to avoid the exclusion of evidence, particularly in criminal cases. Also, as more scientific studies and methodology were brought to bear in toxic and pharmaceutical based tort actions, courts struggled to permit the use of innovative science to establish causation.

In the period immediately proceeding Daubert, some courts, lacking consistent doctrinal standards, opted to treat close questions of admissibility of scientific evidence as matters of "weight" to be resolved by the trier of fact, typically a jury. Some trial judges applied the highly subjective probative value/prejudice balance of Rule 403 to resolve contests over the admissibility of scientific evidence. This relaxed approach placed a premium on the securing of a favorable expert witness and led to the muchcriticized emergence of the hired gun expert.2

Regardless of one's view of the continued efficacy of Frye, the controversy engendered by the use of confrontational experts opining on unusual, and sometimes novel, issues of scientific evidence created a demand for clarification. Not only was there division among the federal circuits, but varying admissibility standards promulgated by state courts led to claims of forum shopping. Thus, the time was ripe for an authoritative pronouncement.

The sweep of *Daubert*

There is continued debate about the sweep of Daubert and its impact on the existing law of evidence. Two points, however, are clear. Daubert both dispels any doubt that Federal Rule of Evidence 702 supersedes Frye and significantly enlarges the role of the trial judge as the arbiter of the admissibility of scientific evidence.

In place of Frye's general reliability standard the Court fashioned a more elaborate inquiry for the trial judge to determine the scientific validity of proffered evidence. The Court pointed to four, non-exclusive, factors: (1) testability; (2) subjection to peer-review; (3) known or potential rate of error; and (4) widespread acceptance (a factor closely akin to the discarded Frye standard). An overarching and separate requirement for scientific evidence, even if found reliable, is that it be relevant, i.e. that it bear upon and materially advance

the resolution of a fact in issue.

With respect to the role of the trial judge, Daubert is quite explicit. Judges must be more active in screening expert scientific testimony, hence the notion of judges as gatekeepers. Are most judges adequate to the task? In the view of certain commentators, judges, despite "their general enthusiasm and diligence tend to be highly resistant to the sort of learning Daubert demands."3 In partial response to this concern, the Federal Judicial Center, in 1994, published a guide for federal judges. This publication, Reference Manual on Scientific Evidence, itself has become a source of controversy with the organizations representing plaintiffs voicing criticism of the manual as defense-oriented and a misinterpretation of Daubert's teaching.

The Supreme Court has attempted to flesh out the Daubert framework in subsequent decisions by expanding the doctrinal basis underlying Daubert's reliability/relevancy approach. In late 1997, the Court decided Gen. Elec. Co. v. Joiner4 which involved a claim by a worker for alleged illness stemming from toxic exposure. The trial judge in Joiner denied admissibility to the plaintiff's expert's conclusion of causation because it was based, in part, on extrapolation from animal studies. The Eleventh Circuit Court of Appeals reversed, noting that the Federal Rules of Evidence demonstrate a preference for admissibility and, thus, require "a stringent standard of review."5

In reversing the court of appeals, the Supreme Court aligned itself strongly on the side of the trial judge by mandating that evidentiary rulings made at trial be reviewed under an abuse of discretion standard. Moreover, the Court explicitly extended the reach of this lenient standard to the trial court's acceptance, or rejection, of both the conclusions and the methodology of the expert. Additionally, the Court stated that the trial judge's discretion is not controlled by "the ipsi dixit" of the expert.

^{2.} See Huber, Galileo's Revenge: Junk Science in THE COURTROOM (1991). For a reply to Huber, see Chesebro, Galileo's Retort: Peter Huber's Junk Scholarship, 42 Am. U.L. Rev. 1637 (1993).

Conley and Peterson, The Science of Gatekeeping, 74 N. C. L. Rev. 1183, 1205 (1996).
 522 U.S. 136 (1997).

^{5.} Joiner v. Gen. Elec. Co., 78 F.3d 524, 529 (11th Cir. 1996).

The judge's role

In a more recent decision, the Supreme Court claborated further on the scope of the trial judge's role as the gatekeeper of the evidence. In March 1999 the Court issued its opinion in Kumho Tire Co. Ltd. v. Carmichael,6 a products liability action brought for recovery of injuries resulting from a tire blow out. The plaintiffs' proof of causation rested exclusively on the testimony of its expert who opined on the tire's defectiveness. The trial court, applying its view of *Daubert*, excluded the expert's testimony because it found insufficient indications of reliability, i.e., a sufficient scientific basis for his opinion. The court of appeals reversed, ruling that the subject of the expert's opinion, tire technology, fell outside Daubert's scope and its rigorous standards for the admissibility of scientific evidence.

The Supreme Court in Kumho Tire again championed the trial judge's discretionary gatekeeping role. The Court emphasized that Rule 702 makes no distinction between types of specialized knowledge, whether "technical" or "scientific." Daubert addressed only scientific knowledge because that was what was at issue in that case. But Rule 702, as interpreted in Daubert, imposes a reliability finding as a prerequisite for all expert testimony in areas beyond the knowledge and experience of lay jurors.

The Court also noted that Daubert's list of criteria intended to guide the trial judge's discretion was not exclusive. In discharging its duty to determine reliability and relevancy, the trial court is extended considerable latitude, not only in the acceptance or rejection of the expert's opinion, but also in the evaluation of the factors leading to that conclusion. Under an abuse of discretion standard, the trial judge could not be faulted for his rejection of the tire expert's opinion and, in the view of the Supreme Court, the court of appeals erred in second guessing that determination.

The Supreme Court's decision in *Kumho Tire* represents a continuation of Joiner's expansive view of the trial

judge's role in applying Daubert's teaching. These Daubert-implementing rulings provide at least three clear interpretive guidelines under Rule 702. First, the range of subjects to which an expert's opinion is directed, and which is subject to judicial scrutiny, is not limited to the purely scientific so long as the methodology is scientific-based. Second, the trial court may extend its gatekeeping role to the expert's conclusions, not simply the expert's methodology. Finally, the trial judge's discretionary authority of acceptance or rejection is subject to reversal only if arbitrary and lacking any record support.

Daubert and its progeny have significantly affected the standards for admissibility of scientific evidence under Rule 702. But these decisions were issued by the Supreme Court under its supervisory power and are, thus, binding only on federal courts. However, Daubert's emergence has led to repeated challenges to Fryebased standards historically followed in state courts. The result has been mixed. Since the overwhelming majority of states have adopted a counterpart of Rule 702, Daubert's interpretation of the rule, while not entitled to deference, has caused most state courts to reexamine the decisional underpinnings of the norms for admissibility of scientific evidence. Other states, notably Florida, have rejected the lure of Daubert and have elected to stay with the Frye test.7 Some states have adopted Daubert as consistent with Rule 702 while others have found Daubert "instructive," but not necessarily required, of trial courts.

The controversy over the merits of Daubert continues in academia with some critics questioning whether trial judges possess a sufficient level of scientific sophistication to assume the gatekeeping role in determining complex scientific issues. Protagonists on both sides of the tort reform debate also dispute whether Daubert places too much power in the hands of the trial judge, whose rulings to exclude expert opinions, particularly in products liability cases, may deprive a plaintiff of redress at the

hands of a jury. Even in the federal system, where *Daubert*'s general application is not open to question, appellate courts, in particular, continue to struggle with "the enormous power [of a trial court] to foreclose submission of a party's case to a jury on the basis of a threshold determination of nonreliability of opinion evidence."8

New challenges

Despite the increase in rulings at both the federal and state level that seek to map the standards and define the limits for admitting scientific evidence proffered through experts, the problem is far from being resolved. There are two factors that hinder the effort to formulate a consistent framework for testing the admissibility of scientific evidence. The first is the evolving nature of the scientific knowledge as it is brought to the courtroom; the second is the highly subjective judgment brought to bear under a gatekeeper construct. Each of these factors deserves elaboration.

For at least the past 20 years, expert testimony has become increasingly more complex as it is directed to a variety of technical and scientific issues. Presentations such as epidemiological studies presented in toxic exposure cases and product liability cases are often based on cutting-edge science. The emergence of DNA evidence as a forensic tool for identification purposes and as a prediction of physical and emotional abnormality is a good example of how knowledge outstrips the ability of courts to accommodate its implications. DNA matching evidence, once viewed as controversial, is now readily accepted for identification purposes. The scientific basis for this evidence is now so well established that its admissibility is sanctioned by statute in many jurisdictions with only the projection of a random match left to expert opinion. The current state of the law seems to sanction the general

^{6, 119} S.Ct. 1167 (1999).

Flanagan v. State, 625 So.2d 827, 829 (Fla. 1993).

^{8.} In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 733 (3rd Cir. 1994) cert. denied 513 U.S. 1190 (1995).

scientific basis for DNA identification by permitting only the challenge to individual results.

DNA evidence as a prediction of genetic influence on physical and emotional abnormality is just now in the early stages of cautious development. Yet, it is now generally expected that within five years the Human Genome Project, sponsored by the Department of Energy and the National Institute of Health, will have succeeded in completely mapping and sequencing the human genome, a sequence of three billion characters. The evolving understanding of the underlying causes of thousands of genetic diseases, including many forms of cancer, will pose significant new responsibilities for health care providers and pharmaceutical companies. With litigation likely, however, whenever new legal relationships are created, advances in genetic science will bring to the courtroom an array of expert witnesses opining on the emerging science of genetics. The opinions they will give (and the counter views which will inevitably arise) will occur on the developing edge of science. Will testability, general acceptance, and peer review continue to be appropriate criteria for determining the admissibility of such testimony?

Daubert's elaborate constraints may prove too rigid to accommodate the novelty of these innovations when offered in the courtroom in cuttingedge cases. It seems reasonable to insist that the current doctrinal framework spawned by Daubert be flexible enough to accommodate "novel" evidence. Yet, at the same time, the prospect of "new" scientific learning presents the risk that practitioners of junk science will seek to enter the courtroom to take advantage of the lack of a formalized body of knowledge. The real challenge for gatekeeper judges in the future will be to balance these competing considerations.

The second, and equally challenging, consequence of the *Daubert* standards is the highly subjective duty im-

posed upon the trial judge. As the gatekeeper, the trial judge is expected to screen expert testimony to insure that the jury does not consider it unless it is relevant and reliable. Daubert's underlying rationale is a sound one: lay jurors should not be exposed to unfiltered scientific or technical testimony that may adversely influence their findings of fact. But this rationale is built on two underlying assumptions: (1) that the trial judge is more knowledgeable in assessing complex scientific testimony than is the average lay juror and (2) that each judge brings to the specific task of gatekeeping a general attitude or philosophy concerning the level of scrutiny appropriate for scientific gatekeepers. Experience, however, has demonstrated that judges are not fungible. Intelligence aside, judges vary considerably in how they view their role in the courtroom; active or passive, dominating or deferential to counsel, prone to independent inquiry or content to let the lawyers try the case.

The presence of a significant subjective factor in the gatekeeper calculus poses a real risk of differing results depending on the idiosyncracies or predisposition of the trial judge. Thus, scientific evidence which would gain admissibility in one courtroom might be rejected in another. To make matters worse, an aggrieved litigant seeking to appeal a lower court ruling on scientific evidence will be required to overcome the highest standard of review-abuse of discretion. Moreover, it may plausibly be argued that, unlike the reliability prong of Daubert which is fact-intensive, the determination of relevancy is more akin to an issue of law and, thus, not requiring the same level of deference.

Traditionally, the right of review has provided the best guarantee for the correction of errors at the trial level. The higher the threshold of review, however, the more difficult it will be for the appellant to demonstrate error. Since abuse of discretion sets the bar at the highest mark, a trial judge making a *Daubert*-based ruling excluding vital expert testimony is fairly well insulated against

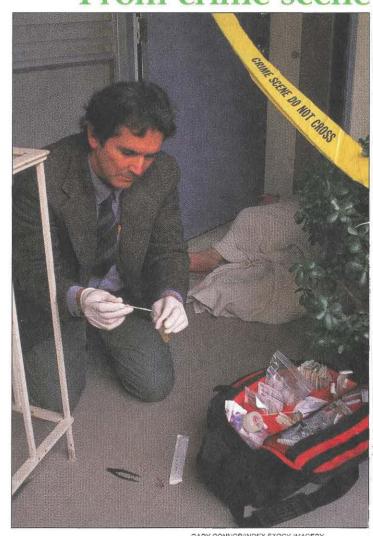
reversal. At least one circuit court of appeals, acknowledging this problem has called for greater scrutiny, or a "hard look" regarding a trial court's rulings that set too high a standard for the admissibility of scientific testimony under *Daubert*. An approach that provides greater scrutiny to rulings of exclusion, however, raises questions about the fairness of examining rulings admitting evidence under a more lenient standard.

The broad discretion given to trial judges performing the gatekeeper role in passing upon the admissibility of scientific evidence apparently was of some concern to at least three members of the Supreme Court who concurred in Kumho Tire. Justice Antonin Scalia, joined by Justices Sandra Day O'Connor and Clarence Thomas, noted that Daubert's grant of discretion is not open-ended. While Daubert's factors "are not holy writ," the failure to apply "one or another of them" in a particular case may be unreasonable and thus an abuse of discretion.

In Daubert and its progeny, the United States Supreme Court accomplished the task of repudiating the Frye rule and replacing it with a standard vesting significant discretion in the trial judge. The new standards, however, have not won acceptance in all state jurisdictions and pose significant problems in application. Courts following Daubert's lead will be required to deal with a fundamental shifting of the responsibility for dealing with suspect scientific evidence. The contest for admissibility will be less and less a competition between opposing experts and more and more the independent responsibility of the gatekeeping judge. It remains to be seen whether this expanded duty assigned to the trial judge will disturb the traditional role of the fact finder as determiners of the weight of testimony. Therein lies the challenge facing litigators and judges as DNA science evolves. 414

From crime scene

INTEGRATING TECHNOLOGY into the **CRIMINAL** JUSTICE SYSTEM



GARY CONNOR/INDEX STOCK IMAGERY

pon reading about the use of DNA technology to exonerate an individual wrongfully convicted of rape and homicide, United States Attorney General Janet Reno raised concerns about the extent to which similar cases existed.1 In April of 1997, representatives from the

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broad spectrum of the criminal justice system met to discuss issues related to the future of forensic DNA technology. After they identified the significant breadth and scope of those issues, the Attorney General re-

The National Commission on the Future of DNA Evidence, established by Attorney General Janet Reno in 1997, is charged with finding ways to ensure the effective use of DNA evidence.

by Christopher H. Asplen

quested that the National Institute of Justice establish a national commission to examine the future of DNA evidence and how the Department of Justice could best encourage its effective use. Since its creation the Commission has examined issues that

reach beyond the Attorney General's original questions about postconviction DNA application to ensuring a more effective integration of the technology into the criminal justice system.

The Commission is chaired by

to courtroom



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Shirley S. Abrahamson, Chief Justice of the Wisconsin Supreme Court. The other commissioners represent the judiciary, prosecutors, the defense bar, law enforcement, the scientific community, laboratory directors, academia, the medical exam-

iner community and victim's rights advocates. (See "The commissioners," page 147.) The Commission's purpose is to make recommendations to the Attorney General that will maximize the value of incorporating DNA technology into the criminal justice system. To accomplish this it has identified five focal areas and established corresponding working groups: Postconviction, Crime Scene Investigation and Evidence Collection, Legal Issues, Laboratory Funding, and Research and Development. Each working group consists of experts in diverse fields who conduct research, examine specific areas, develop guidelines, and ultimately provide the full Commission with information and analysis for deliberation before it makes recommendations to the Attorney General. This article discusses these working groups and describes some of the specific issues being examined.

Postconviction

A convicted individual's continued assertion of innocence is not new to the criminal justice system. The averment of significant "after discovered evidence" is familiar appellate practice. However, the application of DNA technology to previous

Because the Commission is still in deliberation, the opinions expressed here are not necessarily those of the Commission, but rather of the author. Further information about the Commission, copies of the reports it has issued, and proceedings of its meeting are available at www.cip.usdoi.gov/pii/dna/

www.ojp.usdoj.gov/nij/dna/.

1. See Connors, et. al., Convicted by Juries, Ex-ONEATED BY SCIENCE: CASE STUDIES IN THE USE OF DNA EVIDENCE TO ESTABLISH INNOCENCE AFTER TRIAL (Washington, D.C.: U.S. Department of Justice, 1996). convictions may provide a certainty that neither defense nor prosecution is accustomed to in appellate procedure. In these cases, the determination of actual innocence may be achieved, as compared with presentation of evidence that simply suggests the possibility of a different result by a different jury. Because of the level of certainty offered by DNA technology, the decision of whether or not to oppose a motion requesting postconviction relief may now rest on a new, more secure foundation of knowledge.

The implications of DNA technology are most evident in the area of postconviction DNA appeals, as it applies to specific cases and in its broader impact on the criminal justice system. Not only is the Commission examining the specific, scientific application of DNA technology to previously adjudicated cases through the development of postconviction recommendations, it is also considering the effect that this technology may have on our approach to changes in statutes of limitations for filing appeals and charges. The latter issue arises because DNA samples last indefinitely, beyond the periods of time permitted for such filings.

In September 1999, the Commission presented the Attorney General with a report titled Postconviction DNA Testing: Recommendations for Handling Requests. These recommendations will serve criminal justice practitioners as guidelines for analyzing appeals in which DNA may be determinative of actual innocence. The recommendations, unanimously approved by the commissioners, provide a framework and scientific basis on which practitioners can make fully informed decisions and develop appropriate legal approaches. Separate chapters are tailored to the needs of prosecutors, defense attorneys, the judiciary, forensics laboratories, and victim advocates.2

Crime scene investigation

The unrealized potential of DNA technology is most evident in the area of crime scene investigation.⁸ Historically, forensic uses of DNA

technology developed on two ends of a spectrum: On one end was the development of a laboratory technology that was robust and reliable for application in the criminal justice system. The other end of the spectrum was the courtroom application of DNA technology and the "admissibility wars." While significant resources were being allocated to these areas, few were dedicated to educating law enforcement officials, who are responsible for identifying, collecting, and preserving the evidence.

In the United States, forensic DNA technology developed primarily as a prosecutorial weapon, rather than an investigative tool. Unlike the use of forensic DNA evidence in Great Britain, which found its first application in the context of an "intelligence screen" of 4,582 people, DNA evidence was used in the United States primarily to confirm the identity of a suspect already under suspicion. Without a socially and legally permissible mass testing investigative technique and an offender database system, little opportunity existed to harness DNA's ultimate investigative power-its application to non-suspect cases. DNA evidence became something prosecutors requested from law enforcement to prove their case, not something police used to identify and arrest perpetrators.

The advent of the Combined DNA Index System (CODIS) database (discussed below) created a new paradigm of investigation for law enforcement. While several years ago it made no investigative or financial sense to request DNA analysis in cases with no suspect, the introduction of database capabilities significantly changed this situation. However, current use of this technology falls far short of its potential.

Efforts of the Crime Scene Working Group and testimony from the law enforcement community has allowed the Commission to identify significant obstacles to effective use of DNA evidence by law enforcement officers to solve crimes. Of particular concern is the lack of educational resources to ensure proper identification, preservation, and collection of

appropriate biological evidence that could yield a perpetrator's DNA profile. Evidence not identified at the crime scene may not be collectable at a later time, due to destruction by environmental factors or other investigative procedures. Improperly collected evidence may generate confusing, less discriminating, or even inaccurate results.

The working group developed an educational pamphlet that was unanimously approved by the Commission for distribution to every law enforcement officer in the country. What Every Law Enforcement Officer Should Know About DNA Evidence (September 1999) explains the basics of DNA technology in simple terms, and outlines fundamental identification, preservation, and collection issues. It also educates officers about CODIS.4 The recommendation for such a wide distribution recognizes the importance of first responders in evidence collection, and encourages management to acknowledge the importance of funding for education and DNA testing.

Through the working group, the Commission is also developing a more extensive, computer-based curriculum for training officers in DNA collection techniques. We anticipate that this training module will be made available on both CD ROM and via the Internet for incorporation into academy curricula and inservice training programs.

Laboratory funding

Increasing the integration of DNA technology into the investigative process has significant implications for forensic laboratories, most of whom still struggle to meet the demand of cases analyzed for courtroom presentations. In addition, the advent of CODIS has created a national backlog of more than 1.3 million unanalyzed samples, one million of which have not even been collected

4. Supra n. 2.

^{2.} Available from the National Criminal Justice Reference Service, 800-851-3420 or on the Commission's website www.ojp.usdoj.gov/nij/dna/.

^{3.} FBI Laboratory Forensic Science Systems Unit, 1998 CODIS DNA LABORATORY SURVEY (Washington D.C. January 1999).

from convicted offenders.⁵ One problem is that these laboratories were never designed for high volume testing. Further, as the scope of crimes specified by state convicted offender statutes expands, the volume of database samples to be analyzed will increase dramatically. The Commission is providing guidance by first examining the CODIS backlog and then considering the broader issue of laboratory capacity in the context of expanded use by the law enforcement community.

The CODIS backlog. In 1990, individual states joined with the Federal Bureau of Investigation to embark on the most significant advance in criminal investigation in the twentieth century: the establishment of the Combined DNA Index System (CODIS). Through CODIS, law enforcement agencies can compare DNA samples from biological evidence found at a crime scene to DNA profiles stored in convicted offender databases and rapidly identify perpetrators of the most serious crimes. So valuable is this technology that every state in the country has now passed legislation establishing a CODIS da-

tabase system and requiring offenders convicted of certain crimes to provide DNA samples. Because state DNA laboratories cannot process database samples quickly enough, however, criminals who should be identifiable through CODIS remain free to re-offend. The estimated backlog of CODIS samples is six years.

Currently, the CODIS database contains about 230,000 convicted offender profiles.⁶ This relatively limited volume allows the system to identify a perpetrator for approximately every 1,000 offender samples maintained in the system. Some states report an even higher "hit" ratio.

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^{5.} Supra n. 3. 6. Id.

Florida, for example, generates approximately one "hit" for every 300 offender samples. In the United Kingdom the Forensic Science Service reports that their database system currently maintains a database of more than 600,000 samples and receives between 300 and 500 hits per week.

Most of the 230,000 DNA profiles currently in the CODIS system were analyzed by a method of DNA analysis that is rapidly becoming outdated. That method, called Restriction Fragment Length Polymorphism (RFLP) testing, was the first method of forensic DNA analysis to be introduced in the courts. Because of certain limitations, the RFLP method is being replaced by a newer technology, now validated in the forensic community, called Polymerase Chain Reaction using Short Tandem Repeat markers (PCR-STR). But the RFLP and STR methods do not produce comparable DNA profiles. The blood or saliva samples taken from individuals convicted of rape, sexual assault, murder, and other serious offenses that remain in storage are now wait-

ing to be analyzed and entered into CODIS using a set of 13 PCR-STR markers that will be sufficient for convicted offender identification into the

next decade.

Some samples have been in laboratory freezers for as long as five years. These are from perpetrators whose blood may have been taken upon conviction but was not analyzed before their release. If that offender reoffends upon release, one of law enforcement's most powerful tools becomes useless. Given the recidivistic nature of many of the crimes for which DNA is collected pursuant to state statute, apprehending a perpetrator through CODIS can effectively prevent crime.

Because of our inability to analyze offender DNA quickly, we find ourselves in a unique position. We can now identify victims who never should have been victimized. Any woman raped or child murdered by an offender whose blood is drawn, but sits in storage for years while he commits other crimes, is the victim of an absolutely preventable crime. If that offender's DNA is analyzed and his profile placed in the system, he can be apprehended upon his first offense out of prison, preventing the victimization of subsequent persons. Yet we currently risk the former scenario tens of thousands of times over each year. It is rare, especially in the criminal justice system, that an infusion of financial resources could have such a measurable effect on crime prevention.

Because of its critical importance, the backlog issue became the subject of the Commission's first recommendation to the Attorney General, and was presented in the spring of 1999.

The Commission recommends the expeditious analysis and input of untested backlogged samples into the CODIS database system, the effective prioritization of offender samples and the encouragement and facilitation of the use of DNA in non-suspect cases. Grants should be established that facilitate the reduction of both collected and uncollected database

samples, that encourage the development of effective systems for the collection of those samples and that provide law enforcement agencies with direction and guidance to effectively use DNA in non-suspect cases. An Advisory Committee should be established that would set criteria and methods for accomplishing these goals. These grants should be administered with the goal of maximizing the effect of the database system while preventing future database backlogs.

Having convicted offender DNA profiles in CODIS will allow law enforcers to solve cases more quickly. Because cases will be solved more quickly, offenders will have less time to re-offend. It will also help solve old cases that appeared to hold no hope of closure for the victims. The expedient identification of offenders through CODIS also saves valuable investigative resources from being squandered on tracking down erroneous leads.

Future laboratory capacity. The Commission will continue to discuss laboratory funding issues based on its vision of effective laboratory capacity, and an ability to process sev-

DNA profiling vs. fingerprints

DNA is similar to fingerprint analysis in how matches are determined. When using either DNA or a fingerprint to identify a suspect, the evidence collected from the crime scene is compared with the "known" print. For example, if the evidence found at the crime scene is an individual's right thumb print, when a suspect is identified, his right thumb print (or the "known" print) would be compared to that evidence.

Similarly, when DNA testing is performed on crime scene evidence, it is performed on certain locations ("loci") in a DNA sample. When a suspect's DNA is analyzed, it is analyzed at the same loci in order to make a valid comparison. In both DNA and fingerprint analysis if a single feature of the DNA profile or fingerprint is different, it is consid-

ered to be "an exclusion" and not to have come from that suspect.

Because the DNA contained in cells constitutes the chemical blueprint for that person's entire biological make-up, it can potentially provide a broader range of information about an individual than can a fingerprint. For example, investigators use current technology to determine gender from DNA evidence whereas a fingerprint that cannot be found in a database remains of unknown gender. So while the current forensic DNA database identifies individuals based on loci to loci comparison, future applications of DNA technology has the potential to add significantly more information about the evidence than can the fingerprint.

—Christopher H. Asplen

eral different classes of cases.

First, the system should process case analysis samples in a timely manner. Laboratories should not be in the position of prioritizing samples based on trial dates or the demands of prosecutors. Rather, laboratories should have the resources to process samples in a time frame consistent with the use of DNA as an effective investigative tool. The Commission will estimate that time frame and the level of funding that it would require.

Second, the system should achieve a zero backlog of offender database samples and be able to process such samples at a speed that maximizes the effectiveness of the database system and prevents future backlogs. The optimal system also assumes the appropriate prioritization of database sample analysis assuring that individuals on probation and parole (and, as such, capable of re-offending) are tested and entered into the system before those serving lengthy sentences.

Third, as stated in the section on crime scene investigation, laboratories should have the resources to process non-suspect cases in a timely fashion. While it is obvious that the database's ability to solve non-suspect cases is its most important purpose, there is a concern that we are furthest away from accomplishing that goal, given the other pressures on laboratory resources.

Finally, laboratories should have the resources to process old, unsolved cases. The database system has the potential capability to close many previously "unsolvable" cases if law enforcement is willing to apply the technology to unsolved casework.

Legal issues

In a March 8,1999 request to the chair of the Commission, Attorney General Reno identified several "profound" privacy issues for consideration by the Legal Issues Working Group.

One issue is the retention of DNA samples after testing has been com-

pleted. In many instances the biological sample is stored indefinitely. Given the changing nature of DNA technology, capabilities may be developed that allow analyses that were not anticipated at the time of sample collection. What are the possibilities and implications of such a dynamic? What are the legal issues and analyses that must be considered for us to maximize this technology in a way that protects our citizens but does not erode our essential rights of privacy? These questions remain under consideration.

A second issue identified by the Attorney General involved DNA testing of arrestees vs. testing only convicted offenders. While still considering the constitutional implications of such a proposition, the Commission issued an interim recommendation on the subject, stating:

The Department of Justice should not advocate a policy supporting arrestee sampling unless 1) the convicted offender database backlog is substantially eliminated, 2) significant resources are allocated for the analysis of non-suspect cases, and 3) sufficient funds are made available for the collection and analysis of arrestee samples.

While recognizing an investigative value to arrestee testing, the Commission was concerned about the effect arrestee sampling would have on a laboratory system already struggling to keep pace with the testing of convicted offenders, a significantly smaller number of samples.

A third topic under consideration is the issue of statutes of limitations as they apply to both the filing of charges and the filing of appeals. Given the power of DNA technology to investigate crimes that occurred beyond many state's statutes of limitations, the arbitrary allocation of five or ten years to the investigative process may be unfair to victims of crime who may now be able to have their crimes solved, but for the statute of limitations. Likewise, for defendants wrongly convicted but who may be exonerated by DNA evidence, time limits on the appeals process established before this technology was implemented are hardly appropriate.

Research and development

The Research and Development Working Group examines issues that need to be addressed from a technology perspective as the Commission endeavors to identify law enforcement's needs. The criminal justice community needs to know what tools will be available at the crime scene. Will police have portable units to take to crime scenes to do on-scene DNA analysis and will they be able to connect directly to the database? Will the technology exist in the near future to create a physical description of a perpetrator based on a crime scene DNA sample? As we increase our ability to generate results from even smaller samples (a DNA profile may be obtained from a single cell), we must be able to distinguish between the collection of samples likely to yield the identity of the perpetrator and those likely to mislead an investigation.

The financial resources allocated to laboratories is obviously dependent upon future technological developments. The continued substantial commitment to STR technology needs to be based on the confidence that STRs will remain the most efficient and effective technology available. The implications of the forensic use of automation, miniaturized "chip" technology, and other advances need to be considered in order to evaluate their future effectiveness in the criminal justice system.

By identifying and examining the various issues associated with forensic DNA, the National Commission on the Future of DNA Evidence can facilitate a more effective application of this technology, expediting its usefulness as a crime-fighting tool while encouraging public trust in the system. The pro-active approach to these topics, through the Commission's efforts, will ensure that the further integration of this technology will be accomplished with broad based input, thoughtful consideration, and effective analysis of the relevant issues. XX

^{7.} U.S. Department of Justice, Automated DNA Typing: Method of the Future (Washington, D.C.: U.S. Department of Justice, 1997).

COMPLEX SCIENTIFIC EVIDENCE and the JURY

DNA—deoxyribonucleic acid, the chemical molecule inside cells which carries biological information. DNA is a double stranded molecule held together by weak hydrogen bonds between complementary base pairs of nucleotides (Adenine and Thymine; Guanine and Cytosine). This molecule carries genetic information from parent to offspring.

Genome—one copy of all the DNA found in each cell of an organism. The human genome is composed of three billion base pairs of DNA packaged as 23 chromosomes. There are two copies of each [chromosome] in a cell, one copy from each of your parents. The genome contains the organism's genes, the instructions for building that life form.

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GORDON M. GRILLER is court administrator, Arizona Superior Court in Maricopa County and a member of the Board of Directors of the American Judicature Society. hese definitions of DNA and genome, two scientific concepts at the heart of this issue of *Judicature*, seem rather straightforward and simple. One may think that even without scientific background and learning, these concepts can be readily understood, perhaps with a few additional definitions, or a little more explanation from someone

knowledgeable. But as the twentieth century draws to a close, the U.S. Human Genome Project moves closer to its goal: determining and mapping the complete sequence of DNA in the human genome by the

The authors wish to thank Timothy D. Keller, a law researcher for Judge Robert D. Myers, and Richard Teenstra, assistant director of the Maricopa County Superior Court Law Library, for their assistance.



Increasingly complex scientific issues, such as genetics, will further tax the jury system. Courts can and must seek new ways to help jurors cope more effectively

by Robert D. Myers, Ronald S. Reinstein, and Gordon M. Griller

year 2003. The implications of the Project's work for courts and the entire legal system are enormous:

2. Denno, Legal Implications of Genetics and Crime Research, in Bock and Goode, eds., GENETICS OF CRIMINAL AND ANTISOCIAL BEHAVIOUR 235 (Chichester, N.Y.: Wiley, 1996). The HGP's ultimate goal is to discover all of the more than 80,000 human genes and render them accessible for further biological study.... Information obtained as part of the HGP will dramatically change almost all biological and medical research and dwarf the catalog of current genetic knowledge. Both the methods and data developed through the project are likely to benefit investigations of many other genomes, including a large number of commercially important plants and animals. In a related project to sequence the genomes of environmentally and industrially interesting microbes, in 1994 DOE initiated the Microbial Genome Program. For this reason, in addition to the DOE and NIH programs, genome research is being carried out at agencies such as the U.S. Department of Agriculture...and the private sector. In a

departure from most scientific programs, research also is being funded on the ethical, legal, and social implications (ELSI) of HGP data.1

Potential government and private sector applications of this knowledge-gene therapies, gene transfers, genetic screening, and new biotechnologies-ultimately will give rise to a myriad of disputes that will make their way into the courts for resolution. The legal issues involved in these controversies, and the evidence that underlies them, will be far more complex than the two brief definitions of DNA and genome at the outset of this article. As judges and lawyers ready themselves for this growing level of scientific evidence, one principal justice system decision maker is largely unprepared...the trial juror.

Already, the most familiar form of genomic evidence, DNA "fingerprinting" (or "profiling," or "typing") in criminal cases, is widely admissible in state and federal courts, by court decision or legislation. The possible uses of genomic evidence, however, are not limited to criminal matters. Some states have already enacted legislation regulating health insurers' use of genetic testing data. Disputes involving insurance coverage, medical malpractice, product liability, toxic torts, employment discrimination, paternity, privacy, and intellectual property will become increasingly complex as the knowledge of not only human, but plant and animal genetics, and the practical applications of that knowledge, become more widespread. As one commentator has said, it is "not whether genetic evidence will ever be admitted into court, but when and under what kinds of circumstances."2

Against this backdrop, the ability of juries to adequately understand genomic evidence, distinguish between and resolve contradicting opinions of expert witnesses, and properly apply the law to the evidence is being called into question. Some court watchers believe juries are not competent to resolve scientific evidence issues, and matters of complex scientific evidence should be removed from them.

^{1.} Department of Energy, Office of Biological and Environmental Research, Life Sciences Division, Human Genome Research: An Introduction (visited Sept. 2, 1999) http://www.er.doe.gov/ production/ober/hug_top.html>.

Others argue that the societal values represented by both criminal and civil juries are too important to forego, and that the common sense approach jurors bring to disputes equip them in a unique, capable manner to comprehend novel and complex scientific evidence. In reality, the truth likely lies somewhere in between. Yet, there is little doubt that increasingly complex scientific issues have the potential to further tax the jury system, and that courts must seek new ways to help jurors deal with scientific evidence. To do so, courts will have to promote an active learning environment within the courtroom-in effect, turn courtrooms into classrooms.

This new approach to jury trials is under way in some states today, pioneered by Arizona in its far-reaching 1995 jury rule changes including permitting jurors to ask questions, take notes, and in civil cases allowing jurors to discuss the evidence during the trial.3 Arizona's objective: improve the experience and decision making of jurors by redefining their role from passive observers to active participants, using applied, proven adult learning methods, and permitting information to unfold during the trial in more meaningful and understandable ways-in other words, to increase the potential of the "search for the truth."

As research on Arizona's jury reform experience progresses, there is growing evidence that the courtroom, turned juror-friendly classroom, is more conducive to juror comprehension and promotes ease in understanding complex concepts and data. If such is the case, must others wait for statewide system changes? The simple answer: no. Courts and lawyers already possess the means and discretion to enable juries to better carry out their vital roles. Judges and lawyers can independently recognize their roles as educators by embracing ground breaking jury reforms and introducing them in their own courts. These reforms will become increasingly important as genomic evidence appears ever more routinely in America's courtrooms.

Juries and complex cases

Over the past 30 to 40 years, the perceived performance of juries has been criticized, both in high-profile criminal cases and in complex civil litigation in antitrust, securities, intellectual property, and product liability cases. Critics have questioned whether a jury of untrained and inexperienced people can be a competent fact finder and decision maker in lengthy trials that require comprehension of substantial quantities of complex scientific, technical, or statistical evidence, and resolving the testimony of duplicative expert witnesses whose opinions conflict.

Moreover, it is alleged, juries in complex trials will have greater difficulty understanding and remembering the court's instructions, and properly applying the law to the facts. Faced with such a burden, say critics, jurors who are untrained in science and technology are ill-equipped for sound fact finding. As a result, critics allege, jurors will base their decisions less on the evidence and a careful consideration of the reliability of expert testimony, than on external cues, such as the perceived relative expertise and status of the expert witnesses, and will be more susceptible to "junk science" and emotional appeals.4

Intuitively then, we would expect juries to have enormous difficulties with the complex legal issues and scientific evidence that will confront the courts as disputes involving the strange, new world of human genetics and statistical probabilities become more commonplace. We would expect, as well, new proposals for replacing juries with such expert bodies as science courts and expert or "blue ribbon" panels. At the same time, however, a growing body of research on juries and their performance in both "simple" and complex cases is giving us a different picture.5 This research, based on case studies and "lab" or experimental studies, shows that jurors, rather than giving up in the face of voluminous evidence and conflicting expert opinions, take their fact-finding and decision-making responsibilities seriously.

The research shows that while cer-

tain elements of complex trials do tax jurors' comprehension and understanding, there is no firm evidence that their judgments have therefore been wrong. Jurors are in fact capable of resolving highly complex cases. These studies have also shown that factors such as length of trial, and evidentiary complexity in itself, are not necessarily the critical factors in jury performance in complex matters. The problem presented by conflicting testimony of experts hired by the respective parties, for example, is present in simple as well as complex cases. Finally, the research shows that jurors, rather than being passive participants in the trial process, are active decision makers and want to understand. Jurors actively process evidence, make inferences, use their common sense, have individual and common experiences that inform their decision making, and form opinions as a trial proceeds.6

What the research shows then, along with the experiments and experiences of active and concerned judges in complex cases, is that the trial process itself may be as much an impediment to jury comprehension and understanding as the complexity of the legal concepts and evidence, or the competencies of jurors. Many factors, including failure to follow instructions, confusing instructions, non-sequential presentation of evidence, "dueling" expert witnesses, evidentiary admissibility rulings, and

3. See Arizona Supreme Court Orders, Nos. R-94-0031, R-92-004 (1995).

^{4.} See Adler, The Jury: Trial and Error in the American Courtroom (New York: Times Books, 1994); Jury Comprehension in Complex Cases: Report of a Special Committee of the ABA Literation Section (Chicago: American Bar Association, 1989).

^{5.} For a review of criticisms of civil jury competencies and the jury research literature, see Lempert, Civil Juries and Complex Cases: Taking Stock after Twelve Years, in Litan, ed., Verdict: Assessing the Civil Jury System 181-247 (Washington, D.C.: Brookings Institution, 1993); Vidmar, The Performance of the American Civil Jury: An Empirical Perspective, 40 Ariz, L. Rev. 849 (1998); Cccil, Hans and Wiggins, Citizen Comprehension of Difficult Issues: Lessons from Civil Jury Trials, 40 Am. U. L. Rev. 727 (1991).

Hans, Hannaford and Munsterman, The Arizona Jusy Reform Permitting Civil Jusy Trial Discussions: The Views of Trial Participants, Judges, and Justice 1988, Nucl. Phys. B 11, Reform 349 (1999)

rors, 32 U. Mich. J.L. Reform 349 (1999).
7. See Dann, "Learning Lessons" and "Speaking Rights": Creating Educated and Democratic Juries, 68
IND. I.J. 1229 (1993).

attorney strategic errors, affect the jury's ability to follow and comprehend complex evidence. Researchers, and increasingly many progressive courts, suggest that reforming and improving the "decision making environment"8 can improve not only jury comprehension and performance, but juror satisfaction with their trial experience.

Challenging the current model

The Arizona Supreme Court's Committee on More Effective Use of Juries recognized these issues when it made 55 recommendations to reform the jury system, many of which

resulted in the officially adopted comprehensive jury reform rules in 1995. In the introduction to Jurors: The Power of 12, its report to the supreme court, the Committee cited "unacceptably low levels of juror comprehension of the evidence" as one of the motivating factors in urging the Supreme Court to adopt its proposed jury reform rules.9 Arizona's reforms, designed to make jurors active participants during the trial, include juror note taking, pre-deliberation discussions of evidence during civil trials, and the right of jurors to ask written questions. The Arizona reforms also

permit judges greater latitude in exercising their inherent powers to provide to each juror preliminary and final written jury instructions, as well as to open up a dialogue between the jurors, the judge, and the lawyers when a jury believes it is deadlocked or needs assistance. The result has been increased satisfaction with the judicial process by judges, lawyers, jurors, and litigants.

For years, jury reforms such as note taking and question asking were opposed on the assumption that jurors would miss crucial pieces of evidence or assume the role of advocate rather than neutral fact-finder. The empirical evidence collected thus far, however, overwhelmingly indicates that such opportunities do not adversely affect the pace or outcome of trials.

It is intellectually arrogant for those in the legal system to assume that lay jurors are incapable of processing complex information. We

It is intellectually arrogant for those in the legal system to assume that lay jurors are incapable of processing complex information.

have all been thrust into a technologically advanced world, and lawyers and judges are hardly better prepared for the task of sifting through scientific evidence than the jury. But common sense suggests that jury reform measures will aid understanding, and jurors themselves support reforms such as those described above.10 We should recognize that it makes little sense to oppose practices that make jurors more comfortable with complex scientific information. To drive the point home, we have often made the observation that it is difficult to imagine an academic setting in which taking notes and asking questions would not be permitted.

Fortunately, the tides are beginning to shift in the debate over jury reform. Already a number of states are adopting new rules; Arizona, Colorado, and California are just a few.11 In New York, much of the reform debate has centered on the selection, administration, and management of the jury, but substantive changes are not far behind. Reforms such as increased jury fees and security, and a juror hotline to report problems have been quite successful. However, the trend in these states and others is to expand beyond administrative concerns and attempt to improve jury deliberations and perfor-

> mance. These grassroots efforts led the American Bar Association in 1998 to adopt a number of jury reform ideals drafted by a Section of Litigation task force as part of its Civil Trial Practice Standards. In adopting these standards, the ABA recognized the need to provide juries, lawyers, and judges with the tools to increase jury comprehension in this era of increasingly complex evidentiary issues.

> However, a complete overhaul of state and local jurisdictional rules is not necessary. These reforms can often be implemented, consistent with existing rules, at the dis-

cretion of the trial judge. Of course, when local rules conflict, those rules control, but most judges possess the inherent power to implement reforms in complex cases. For example, Rule 611 of the Federal (and Arizona) Rules of Evidence permit the judge to control the mode and order of questioning witnesses and presenting evidence. With the number of complex cases dramatically on the rise, judges and lawyers need to collaborate to help the jury become better fact-finders.

A practical guide

Many lawyers and judges seem to have forgotten the proper role of ju-

^{8.} Cecil, Hans and Wiggins, supra n. 5, at 765.
9. JURORS: THE POWER OF 12, Report of the Arizona Supreme Court Committee On More Effective Use of Juries (November 1994).

10. Hans, Hannaford and Munsterman, supra

n. 6, at 371-372.

^{11.} For a review of state jury reform efforts, see Munsterman, A brief history of state jury reform efforts, 79 JUDICATURE 216 (1996); Murphy, et al, Managing Notorious Trials (Williamsburg, Va.: National Center for State Courts, 1998); ENHANC-ING THE JURY SYSTEM: A GUIDEBOOK FOR JURY REFORM (Chicago: American Judicature Society, 1999).

ries. Alexis de Tocqueville, the renowned historian, once said:

[t]he jury...may be regarded as a gratuitous public school, ever open, in which every juror learns his rights,...and becomes practically acquainted with the laws, which are brought within the reach of his capacity by the efforts of the bar, the advice of the judge, and even the passions of the parties...1 look upon the [the jury] as one of the most efficacious means for the education of the people which society can employ.¹²

It is this idea of educating the jury, of treating the courtroom as a class-room, that judges and lawyers alike need to recapture. We urge all members of the legal profession to implement, on their own initiative, the appropriate reforms when cases require an understanding of complex scientific evidence.

Before we discuss individual reforms in more detail, it is important to note the role of judges in rigorously applying the rules of evidence. The judge plays a very important role in improving jury comprehension by appropriately screening evidence and admitting only that which meets the appropriate standards. The judge must scrupulously protect the jury from unreliable scientific evidence.¹³

Jury selection. Lawyers are often criticized for using their peremptory challenges to "dumb down" the jury. In complex cases, however, it is in the best interest of all concerned to select educated jurors and not strike persons based on the extent of their education. While there is little empirical evidence to demonstrate that more educated jurors are struck more often than less educated jurors, there does seem to be an unwritten rule of practice that professionals should be struck when possible. The authors themselves plead guilty to using that approach as trial lawyers.

Perhaps lawyers fear that highly educated individuals will dominate in the jury room and be able to persuade the jury to their side during deliberations. However, preliminary data suggest, and we believe, that jurors take their job seriously and will not be easily persuaded to a position with which they do not agree. ¹⁴ Those

lawyers who believe in "dumbing down" juries should adjust their views accordingly, and recognize the important role of jurors as fact finders and decision makers. Of course, both lawyers and judges must still attempt to detect jurors with prejudices or preconceived ideas, but they should also seek to empanel the best jurors available from the pool.

Juror note taking and notebooks. Of all the reforms discussed, allowing the jury to take notes during the trial must be the most common-sense and least controversial. Nevertheless many jurisdictions just don't get it. Research indicates that note taking does not distract jurors, nor does it create an undue influence on those jurors who choose not to take notes. Judges in Arizona instruct jurors that they are not obligated to take notes, and they tell the jury to pay attention to all aspects of the trial including witness demeanor and the documentary and testimonial evidence.

The vast majority of courts recognize that it is within the sound discretion of the trial judge to permit jurors to take notes. Judges need to thoughtfully exercise their discretion and allow juror note taking in complex cases, and lawyers must urge judges to do so. Jurors need to be encouraged to take an active role in the trial. Allowing the jury to keep track of parties, witnesses, testimony, and evidence by taking notes will empower juries to improve their recall and understanding of all issues, simple and complex.

Jurors in complex cases should also be given a comprehensive notebook containing items such as simplified jury instructions, layouts of the courtroom with the names and locations of lawyers and parties, and glossaries of scientific terms or helpful scientific diagrams, photographs, charts, and background data of all types.

Better jury instructions. Judges historically instruct juries at the end of the trial. There are few rules or cases, however, that prohibit judges from instructing juries earlier. Judges in Arizona provide juries with pretrial instructions that, for example, define the elements of the alleged crime or

define terms such as "negligence" and "fault." This permits the jury to understand the basic legal standards early in the case, refer to them during the trial, and then concentrate on the presentation of the evidence.

Jury instructions should be written in plain English. When drafting jury instructions, both judges and lawyers should avoid unnecessary legal jargon. In Arizona, the state bar's Civil Jury Instruction Committee even includes a linguistics professor from a local university. Jury instructions must also be tailored to the case at trial. Instead of using only pattern jury instructions, judges should work with counsel to draft case-specific instructions that include party names and actual facts in the case, without commenting on the evidence. Instructions should be given early in the case both orally and in writing for maximum comprehension and memory retention. The written instructions should be included in the jury notebook. Jurors need to understand the legal context of the evidence presented, and early instruction facilitates a better understanding of its legal relevance.

Finally, jurors should each be given a written copy of the final instructions and they should be allowed to have the instructions in the deliberation room. Arizona's rules require judges to provide each juror with a copy of all the jury instructions. After all, why should jurors have to pass a single copy when a few dollars can provide copies all around? And where is it written that jury instructions must only be oral?

Permitting the jury to ask written questions. When it comes to issues of scientific evidence, lawyers and judges collaborate to understand and narrow the issues before the court. They ask each other questions to clarify misunderstandings prior to trial, and will confer even during the trial. Yet, once the trial begins, jurors

^{12.} de Tocqueville, Democracy in America 295-296 (Vintage ed. 1945).

^{13.} Daubert v. Mcrrell Dow Pharm. Inc., 509 U. S. 579 (1993).

^{14.} Hans, Hannaford and Munsterman, supra n. 6.

traditionally are not permitted to ask questions. It is time to end this nonsensical practice.

Jury questions should be written and given to court personnel before the witness leaves the courtroom. Counsel should be given the opportunity to object in a sidebar, or outside the hearing of the jury, and the jury should be instructed about the limitations on questions that can be asked. In Arizona, there have been no reports of problems with this type of procedure after thousands of trials over the last four years. A study reported in the March-April 1996 issue of Judicature found that jury questions helped jurors understand the facts and issues, that jurors did not ask inappropriate questions, and that jurors did not draw inappropriate inferences when their questions, due to counsel's objection, for example, were not asked.15

As the comments to the ABA Standards noted, state and federal courts have overwhelmingly recognized that it is within the sound discretion of the trial judge to allow juror questioning of witnesses. We encourage judges and lawyers to experiment with jury questions in complex cases. The empirical evidence, and our own experience, reveals that the fears and concerns about jury questions are unfounded. As two Arizona attorneys recently wrote, "Our experience [with juror questions] reinforces for us the effectiveness of juror questions in keeping the jury engaged and in improving the quality of our own trial presentations. The jurors' questions revealed areas of confusion or concern, enabling us to adjust our presentation accordingly."16

Juror discussion during civil trials. Perhaps one of the most controversial Arizona reforms at the time of its adoption, and still controversial today, is allowing jurors in civil cases to discuss the evidence prior to final deliberation. In Arizona, jurors are carefully instructed by the trial judge that they may discuss the case, so long as all members of the jury are present and they reserve judgment until final deliberations. The general consensus of the Arizona bench and bar is that this reform has been a success. In fact, the Committee on the More Effective Use of Jurors, in its second report to the Arizona Supreme Court (in June, 1998), recommended that the rules be expanded to allow pre-deliberation discussions during criminal trials. As of this writing, however, the supreme court has not adopted that recommendation.

Traditionally, the view has been that permitting jurors to discuss the evidence early in the trial will lead them to make up their minds before hearing both sides. Recent studies suggest that this is not true.17 In fact, some studies have gone so far as to say that requiring jurors to refrain from discussing evidence actually hinders their ability to process information.¹⁸ Pre-deliberation discussion can help improve juror comprehension, improve memory recall, and relieve the tension created by a forced atmosphere of silence with regard to the evidence presented at trial.19

Social scientists report that jurors naturally tend to actively process information as it is received. Therefore, it is not surprising to find that studies show that anywhere from 11 to 44 percent of jurors discuss the evidence among themselves during the trial despite judicial admonitions to avoid such discussion.20 Explicitly allowing pre-deliberation discussions, then, is really an acknowledgment of what often occurs naturally.

Perhaps surprising to some, Arizona's experience has shown that when one individual juror makes a preliminary judgment during predeliberation discussions, that judgment is often tested or challenged by the entire group.21 In United States v. Wexler (1987) Judge Ditter aptly explained that "jurors are concerned, responsible, conscientious citizens who take most seriously the job at hand." Like Judge Ditter, we believe the jurors are more interested in doing justice than in justifying their own loosely based preliminary conclusions, which are frequently subject to modification as a result of group discussions.

A recent study of jury discussions during Arizona trials found that jurors overwhelmingly support this reform and report that it has positive effects.²² Specifically, jurors said that discussions improved comprehension of evidence, that all jurors' views were considered, and evidence was remembered accurately. Additionally, only a very low percentage of participants in the study said that trial discussions encouraged jurors to make up their minds early on. The study also found that, among judges, lawyers, and jurors, support for this reform increases with experience.

Permitting pre-deliberation discussion, more than any other reform, challenges the legal profession's traditional notions of jury behavior, but it is time to recognize the need for juries to have better tools in dealing with complex evidentiary issues.

Independent court appointed or stipulated experts. Unlike fingerprint or ballistic evidence, where it is easier to understand the samples juries are asked to compare, genetic evidence requires juries to sit through conflicting scientific interpretations from expert witnesses presented by the opposing parties. Early presentation of independent experts, either court appointed or stipulated, can help solve many of the problems presented by genetic evidence. Recent surveys suggest that judges favor appointing independent

^{15.} Heuer and Penrod, Increasing juror participation in trials through note taking and question asking, 79 Judicature 256, 260-261 (1996)

^{16.} Cabot and Coleman, Arizona's 1995 Jury Reform Can be Deemed a Success, ARIZONA JOURNAL, July 12, 1999, at 6.

^{17.} See Hans, Hannaford and Munsterman, supra n. 6; Hannaford, Hans and Munsterman, "Permitting Jury Discussions During Trial: Impact of the Arizona Reform" 9 (1998) (unpublished manuscript, on file with the authors).

^{18.} Chilton and Henley, Improving the Jury System, fury Instructions: Helping Jurors Understand the

Evidence and the Law, §II, PLRI REPORTS (Spring 1996) http://www.uchastings.edu/plri/ spr96tex/juryinst,html>

^{19.} Hans, Hannaford and Munsterman, supra n. 6; Hannaford, Hans and Munsterman, supra n. 17; Chilton and Henley, supra n. 18.

^{20.} Chilton and Henley, supra n. 18.21. Myers and Griller, Educating Jurors Means Better Trials: Jury Reform in Arizona, 36 JUDGES J. 13-17, 51 (Fall 1997).

^{22.} Hans, Hannaford and Munsterman, supra

experts in complex cases. However, statistics show that the actual use of court appointed experts is relatively low.23 This situation is unfortunate because there are many advantages to be realized by the use of independent experts. For example, a case involving the admissibility of DNA evidence using a particular type of analysis was recently before the Arizona Superior Court. Both parties agreed to the appointment of a neutral court expert to testify about the procedures used in this analytial method. Substantial saving, in time and money, were realized by the appointment of the court expert. Judicial economy and fairness demand the use of innovative techniques in dealing with admittedly complex scientific issues.

In most jurisdictions trial judges have inherent authority to appoint experts as technical advisors to assist the court. In fact, judges may appoint expert witnesses for testimonial purposes under Rule 706 of the Federal Rules of Evidence and similar provisions in force in most states. However, the use of court appointed experts to serve as a jury tutor on the basics of, for example, DNA evidence, is an under-utilized tool.24 Prerecorded video "lectures" may be another avenue to explore when considering how to educate jurors on issues of "common" scientific knowledge. The basic building blocks of DNA and the basic methods of DNA testing could be simplified and presented to the jury in such a fashion as to make it much less intimidating.25

Many lawyers may argue that "dueling experts" is the model courts should adhere to, based on the adversarial nature of our justice system. However, a recent study found that jurors do not rely on cross-examination of expert witnesses designed to point out flawed scientific methodology. The authors suggest that this is because jurors do not believe lawyers are sincere in their attempts to educate jurors, but rather see cross-examination as the lawyer's attempt to undermine the expert through any means possible.

Independent experts present an

opportunity to not only improve juror comprehension and performance, but also decrease the substantial costs of expert witnesses, and increase judicial economy. The adversarial nature of the trial may be diminished, but that is actually a benefit, not a cost, according to independent experts considering jury reactions to lawyer cross-examination of opposing party witnesses. It is the judge's responsibility to be proactive in ensuring that the trial is a search for the truth, and that it is not about lawyers setting up road-blocks to that search.

Allow a dialogue between jurors, lawyers, and the judge during deliberations. In place of the traditional "pep talk" judges often give to deadlocked juries, Arizona explicitly provides for an opportunity for further instruction by the judge and argument by the parties. Why should the opportunity to educate jurors further stop once deliberations begin? Allowing additional evidence, argument by counsel, or providing further instruction is not problematic, legally or pragmatically. Of course, judges must be careful not to influence jurors and need to limit further inquiries only to those issues that confuse or divide the jury. Once again, there are many cases approving the judge's inherent authority to reopen a case for additional evidence or argument where the jury needs further admissible evidence to reach a verdict, or to determine if a deadlock is unavoidable.27

Opening the courtroom to more creative learning. Increasingly, the Human Genome Project's Ethical, Legal and Social Implications Program is sensitizing the judicial and legal community about the changing rule of the law in light of new genetic discoveries and testing methods. Primers reviewing DNA and genome science have been written, memorable cartoon drawings simplify sophisticated concepts, ²⁸ and video background resources explaining genetics in meaningful non-scientific ways are growing in number.

Further, difficult concepts can be reduced to plain English and conveyed to juries through innovative technologies, including live, videotaped, or interactive Internet-based testimony. These approaches can easily be presented while simultaneously ensuring that complex scientific evidence is afforded the utmost of seriousness.

Educating the jury early in the trial, by using court appointed experts, better written jury instructions, jury notebooks, and basic adult education techniques, will provide a foundation for later testimony of experts presented by the lawyers. Jurors who have been tutored early about complex scientific issues will be in a better position to judge both the content and character of dueling experts.

Who benefits?

Two central participants in the courtroom are the ultimate beneficiaries of reform-oriented jury approaches when heavy doses of scientific evidence are the subject of an unfolding courtroom drama: jurors, and more importantly, litigants. Contemporary behavioral research, and Arizona's jury reform experience, substantiate that comprehension and understanding are significantly enhanced when information is actively processed. Most courts already possess the tools to implement the educational techniques discussed above. Whether through system-wide jury reform or the efforts of individual trial judges and trial lawyers, a more jury-centered trial will not only allow jurors to actively and intelligently participate in the fact-finding and decision-making process, but also give the litigants a better truth-finding forum. I'A

^{23.} Sanders, Scientifically Complex Cases, Trial by Jury, and the Erosion of Adversarial Processes, 48 DEPAUL L. REV. 355, 378-379 (1998).

^{24.} THE EVALUATION OF FORENSIC DNA EVIDENCE 169-171 (Washington, D.C.: National Research Council, 1996).

^{25.} For examples of excellent illustrations and explanations, see Hoagland and Dotson, The Way Life Works (New York: Time Books, 1995).

^{26.} Kovera, McAuliff and Hebert, Reasoning About Scientific Evidence: Effects of Juror Gender and Evidence Quality on Juror Decisions in a Hostile Work Environment Case, 84 J. OF APPLIED PSYCHOLOGY 362, 379-373, (1909)

^{27.} Myers and Griller, supra n. 21, at 16-17. 28. See Hoagland and Dotson, supra n. 25.

EDUCATING **JUDGES** for adjudication of new life technologies

Judges will increasingly be called upon to adjudicate controversies related to genetics and biotechnology.

A series of workshops is helping to prepare them.

by Franklin Zweig and Diane E. Cowdrey

irtually no day passes and no newspaper publishes without reference to new developments in biotechnology, and most have legal implications. A few are studded with ethical controversies. Many portend widespread social adjustments. Because legislatures are slow to act, those controversies can be expected to be brought to court systems for resolution. Courts will become the firstnot the last-resort for both dispute

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grant award. Nothing in this article should be in-

terpreted as reflecting the policies or opinions of

the aforementioned federal agencies.

resolution and policy interpretation during the 21st century's early years.1

Judges, and sometimes juries, will adjudicate controversies related to biotechnology—the ability to invent and influence life forms at the molecular level, technical deployment of reversible and permanent changes to crops, plants, animal life, and the structure and function of human biology.

While economically-relevant civil cases are directly related to the new

1. The economic value of knowing the exact

life technologies, so will be criminal proceedings. The use of biotechnology to engineer brains resistant to addictive disorders, for example, could have vast implications for the criminal justice system and for our rights-based jurisprudence.

America leads the world in biotechnological advances, and is impeded by little regulation. American judges should anticipate that interna-

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ingredients (sequencing) and location (mapreflect the policies or opinions of the Einstein ping) of the human genome is clearly presented Institute for Science, Health & the Courts, its diin Gillis Cracking the Code, Business Magazine rectors, or its sponsors, or the courts of the State of Utah. Support for this article was provided in part by the Office of Biological and Environmental Research, U.S. Department of Energy through grant no. FG02-DE-96ER62170 and by the National Institute of Environmental Health Sciences, National Institutes of Health, U. S. Department of Health and Human Services through an inter-agency agreement for the same

For a perspective on some forecasted implications of life technologies based upon genetic engineering, see the special supplement, Your Bionic Future, 10 SCIENTIFIC AMERICAN (Fall, 1999).

tional as well as domestic parties will paper U.S. state and federal courts and international forums with demands for injunctive relief, damages,

Supplement, The Washington Post, September 27, 1999, at 18-20. The concept of a gene is crucial to all EINSHAC case management and review scenarios. For a clear, digestible, recent overview, see Shreeve, Secrets of the Gene, 196 NATIONAL GEO-GRAPHIC 42-76 (1999).

and criminal law enforcement. How will judges cope?

This article discusses conferences presented by the Einstein Institute for Science, Health & the Courts (EINSHAC) designed to orient 2003 judges by year 2003 to evidence from genetics, molecular biology, and biotechnology. It also describes an impact evaluation of the Western States Genetics in the Courtroom Conference, the ninth in a series of 16 conferences.

The curriculum for the conference series has been well developed and tested. Most conferences are three days, but may vary to accommodate local sponsors' needs and interests. Three types of conferences have been designed: basic genetics training for federal and state judges; specialized conferences on behavioral genetics, biomarkers, and biological property; and policy courts conferences for justices and judges of reviewing forums. With an objective to raise judicial confidence in case management, conferees report that informal contacts with science advisors at the conferences are a valuable educational experience.

Participation in three day, problem-solving conferences appears to have a significant ripple effect and other useful impacts, but must be subjected to better tests as the series proceeds. The results of the impact evaluation also prompt us to ask whether judicial temperament is itself influenced by genetic factors; and whether the judiciary of the future will be selected in part from test results utilizing genetic screening technologies. Whether answered affirmatively or negatively, the courts will find orientation to the new biology indispensable to 21st century case management.

Learning about the new biology

Judges need a special form of science education in order to craft and implement adjudication tailored to novel, complex cases. Audiences at 11 molecular science conferences conducted during the past two years favored a combination of laboratory, science background and judicial applications problems. *EINSHAC*'s three day conferences have delivered genetics, molecular biology and biotechnology curriculum to approximately 1,100 judges. Six more conferences are on the drawing boards for years 2000 and 2001. They will offer to an additional 1,000 judicial participants problem-based, collegial forums to envision causes of action, case content, and novel evidence management.

Powered by an evidence jurisprudence in the United States that recently has imposed upon federal judges a new duty of science and technology gatekeeping—a duty that has in one form or another been adopted by an estimated one-half of state courts—the conference series offers a knowledge foundation to promote case management. The new biology challenges judges with novel, even revolutionary findings, with tests and testing technologies that immediately harness those new findings, and with a generation of expert witnesses that did not exist even five years ago.

Our goal is not to transform judges into arm chair scientists. It is to aid management of cases brought to the courts, to facilitate just resolution of the disputes that turn upon the biological revolution in cases from A to Z—one might say from Adoption, where a demand is now heard for genetic testing profiles, to Zoological Diversity, where introduction of genetically-engineered life forms may be claimed to aid or injure a planetary region's gene pool.

But does it work?

A three day conference linking science, ethics and law is challenging fun for judges years away from Biology 101. But that does not mean its impact will endure. What happens when the rosy glow at conference departure gives way to the next several months' case calls?

To find out, an impact evaluation was developed by the Utah Administrative Office of the Courts, one of the sponsors of the conference convened in October, 1998 for judges from five Western states.² Conducted

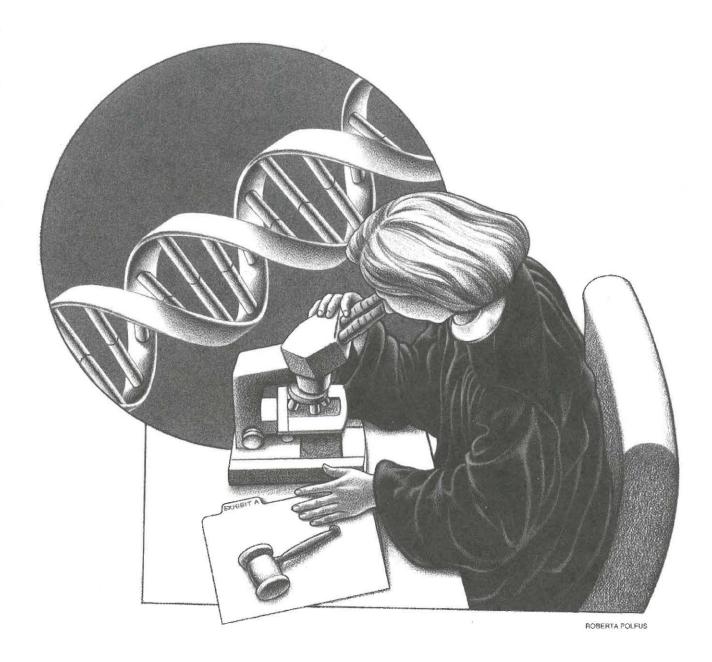
six to ten months after the conference's conclusion by Utah's chief judicial educator, structured personal interviews were used to measure the conference's perceived usefulness and impact. Twenty interviews were conducted from among 80 participants; 16 were deemed usable for the evaluation report. Names were chosen randomly from sub-samples stratified to assure representation from each of the five states that sent conferees. The objective was to evaluate a single conference's impact from its participants' point of view; just as important, we sought a template for evaluating future conferences' impact during the second tier of genetics in the courtroom offerings, those planned for the first three years of the new century.

The evaluator asked judges from each of the five participating states what they remembered most vividly about the conference; how meaningful retained information and perspectives appeared six months later; whether they applied material acquired at the conference in cases; and to what extent post-conference collegial activities were spurred by conference participation, including continuing study. Judges were also asked if the conference had increased their confidence in managing geneticsrelated cases. In service to brevity, we discuss only general findings and two impact dimensions below.

The full report concludes that judges exhibited from their conference experiences considerable satisfaction, concept durability, and application a half year following the conference. However, we caution about over-generalizing the findings. This was a single conference follow-up and may not be representative of the other conferences.

A qualitative research design was chosen in order to elicit fuller information from conference participants than would have been possible using quantitative research methods. This

^{2.} Cowdrey, "Courts and the Challenges of Genetic Testing: Impact Evaluation Final Report," September, 1999, Administrative Office of Utah Courts, 450 South State Street, PO Box 140241, Salt Lake City, Utah 84114-0241.



study may provide guides for future evaluations using quantitative scales, studies designed to more thoroughly describe and explain the judicial experience at the interfaces of bioscience, ethics and law. An advantage afforded by the Western State's impact evaluation study was that all interview comments were transcribed, making it possible to relate judges' experiences in their own words.

Retained meaning

Not everyone had had the opportunity to use the information in a case since departing the Western States

Conference, but when judges did have a case related to genetics, they reported they were better able to manage it and felt more confident in doing so. Learning theory tells us that if new information is presented in such a way that learners can make connections with old information, learning will occur. Based on the evaluation's interviews, all of the attending judges included in the follow-up sample reported retained recall that held significant meaning for them. Responses tended to fall into one of three categories:

· Specific or general genetics sci-

ence background presented at the conference;

- Philosophical issues that were raised from the material presented at the conference; or
- Judicial and/or legal issues raised from the material presented at the conference.

Judges' answers sometimes fell into more than one of these descriptive categories. For instance, some judges recalled specific genetic technical information—the structure of DNA, for example—and then seamlessly incorporated it into remarks about their work as a judge. Judges

comments, minimally edited and coded by subject numbers to protect identity, therefore, often bridged response categories. The following included both specific and general recall of technical information:

I acquired a better understanding of DNA, what it means, what it can be used for, how it is acquired, than I ever had before...

...In terms of what I got out of it, I felt that I got a much better grasp of technical scientific issues and genetics, and DNA fingerprinting and I think I was able to share those thoughts in a constructive way with the other judges.

Rather than recalling specific, technical information from the conference's science presentations, some participants highlighted philosophical issues that were raised in the course of the Western States' conference curriculum. Some judges reported having raised issues themselves in and following their conference participation. Others found that the conference affected them profoundly and personally:

And the two things I came away with were...one, that the very rich are going to be able to genetically engineer their children. They're going to end up to be a different species than the rest of us. And two, that our legislature, both the state and federal, as we just had proven to us once again, are controlled by special interests, and they are not going to protect us from the life insurance companies and the health insurance companies who are going to use DNA to our detriment.

You know, another judge and I, while we were going through the conference, took some time, probably a couple of hours, and talked about our philosophy of life and the impact that this had on that. It was really an interesting discussion that I won't forget. It just made me sort of marvel at life. At how amazing it is that we live and die and that we can generate human life from this little descriptive code. So that really sticks with me. The ethics of the scientists really sticks with me. I was really impressed and happy to see such integrity and such concern and compassion. You know, people think scientists are sort of test-tube and kind of removed and everything, but these people really do it because they're interested in life, and human beings and life. That sticks with me.

Some participants were more fo-

cused on connecting the information presented with their work as a judge. They reported remembering the implications of the science in the discharge of judicial and/or legal professional responsibilities:

...And as a judge, I've thought about that (free will vs. biological determinism) a great deal in sentencing and dealing with complex problems within our communities, and how much of those are volitional? How much of that activity may in fact be genetically based? So this whole concept of sort of individual free will versus social determinism and genetic determinism is something I think about a great deal since the conference.

There are things that I remember from the conference in terms of the role that genetic evidence is going to play in all kinds of litigation and not just DNA criminal cases, but all these other types of case examples that we discussed at the conference. The context in which it can come up in terms of employment discrimination and you know, civil cases, as well as criminal.

"Ripple effects"

Like ever-widening ripples in a pool stirred by a thrown stone, conference content and perspectives were spread to others, increasing dissemination, and extending conference impact. Among individuals, impact echoes also were detected with respect to participants' heightened interest in continued, personal, scientific learning. Conference ripple effects can be described in three categories:

- Some conference participants shared their information and experiences with their colleagues, both informally and in formal modes.
- Nearly all conference participants reported being more open and interested in information about genetics that they encountered casually; they read the popular press more carefully, including genetics-related items that, prior to the conference, they might have ignored.
- Some conference participants were inspired by the conference to conduct or initiate further genetics study and reading.

Some participants in the first category reported more formal dissemination of conference-based information, as illustrated by the following quote:

...There were four or five of us there (from the same bench) at the conference. When we came back, we gave a panel presentation on the conference...and then we videotaped it so that it's available to the judges that couldn't get to that conference.

In addition to increasing the breadth of impact by discussing the conference with fellow judges, some participants increased the depth of the impact by continuing to educate themselves in the area of genetics:

I've paid lots more attention to them [current news releases involving genetics] than I ever did in the past, simply because now that I have the additional education that I got from the conference, I am more able to understand things and I'm curious, waiting for those breakthroughs, waiting for when they're going to be announcing them, those sorts of things...it's just paying attention to magazine and newspaper articles that I probably would've ignored before this conference.

I did do a lot of additional reading on...one aspect of DNA and.. I did a presentation, from the standpoint of what issues does this raise for some of the medical cases we hear and how, from the perspective of the care provided or treatment provider, and that's what I was reading about.... It was in our packet of articles that we received and I used that packet to get to other articles.

Although the Western States Conference offered no prescriptions or model orders for judicial management of genetics-related evidence, participants offered many comments that pointed to increased confidence in case management generally. A few had been assigned criminal cases and felt more comfortable with the DNA forensic evidence introduced and in managing expert witnesses. Ninetythree percent of the judges reported an increase in their confidence level in presiding over genetics issues. Detailed in the impact evaluation report, several judges noted the conference saved them time when on-point cases arise. Having been provided a baseline of knowledge in genetics, these judges were able to grasp and absorb testimony more quickly, ask relevant questions of witnesses when necessary, and feel more confident about their rulings.

Screening for judicial temperament

Evaluative comments were gratefully received, but they also raised a question. Could it be that self-selection in the decision to accept an invitation to attend an ethics-studded science conference is the dominant variable underpinning the meeting's success? Would another sector of the judiciary be more science-resistant, less favorably impressed with the legal implications?

Answers to these questions must await the evaluation research planned for the next generation of conferences. Using case controls, EINSHAC plans to compare judicial attendees with non-attendees. But we wonder, on the other hand, if the issues advanced simultaneously at meetings and as questions to non-participants might stir the same level of interest. Is there something about the desire to be a judge, and about the art of judging, that elevates interest in genetics?

From the inheritance of intelligence to causes of violence and mental illness to the cure of addictive disorders, behavioral genetics appears to hold special fascination for courts. Perhaps judges expect molecular biology to provide keys to the scourges of human nature and nurture that appear daily in our 30,000 courtrooms. Scientific claims certainly will abound as the map of our genes gives

way to huge numbers of predictive genetic tests, many of them purporting to spot potentials for mental and emotional flaws that will occur later, perhaps decades later, and for some of which treatment forseeably will be available. Pharmacology has produced in recent years a growing storehouse of mood-altering drugs. What if scientists claim the ability to create genetic screening that will predict temperament in general, the durability of judicial temperament specifically?3 Would the public demand it? Would policy makers adopt it? Would judicial appointment screening panels require it? Would a judi-

Disputes rooted in the biotechnologies affecting human nature will be brought powerfully to court in novel claims founded upon a new generation of scientific evidence and biological engineering.

cial candidates' own rights to privacy be vulnerable to assault as an incident of a desire to serve the public from the bench?

Such questions shape one complex scenario selected for small group discussion by some genetics' conferences' judicial planning committees.⁴ In the hypothetical fact pattern, a judicial screening commission requires a predictive genetic test for Alzheimer's Disease and Bi-Polar

tralized Self-Regulation, Accountability and Judicial Independence Under the Federal Judicial Conduct and Disability Act of 1990, 142 U. P.A. L. REV. 25 (1993); and Disciplinary Action Against Judge on Ground of Abusive or Intemperate Language Toward Attorneys, Court Personnel or Parties to or Witnesses in Actions and the Like, 89 A.L.R. 4th 1278 (1991, 1998)

(manic-depressive) Disorder. Both clinical conditions could handicap the dispassionate, detached, objective, even-handed, calm-inducing professional conduct expected of judges in their attempts to resolve disputes. The scenario, in turn, raises all the scientific, legal, ethical, and social issues set in motion by on-rushing advances of molecular biology, biotechnology, and human genetics. Nothing could be more occupationally salient for the bench. Nothing could stir more attentive discussion. But scientific validity is key to the discussion. And a working understanding of the terms used by the scientific commu-

nity is necessary to assess that validity.

We expect that the jury will be out for the next few years as we explore more fully the possible connection between judicial temperament, genetic testing, and civil and criminal case management. This line of future investigation may well help the courts cope with complex issues just around the bend.

An observation ends this brief discussion. In

order to function as adjudicators of issues stemming from scientific manipulation of the new biology, judges, in their own interest, must shop for opportunities to get smart about fields thought long ago to have been abandoned in favor of the law's majesty and power. The law trumps in a constitutional system. Adjudication rules in a democracy founded upon personal rights. But disputes rooted in the biotechnologies affecting human nature will be brought powerfully to court in novel claims founded upon a new generation of scientific evidence and biological engineering. That evidence will be orbited by ethical, legal, and social issues that will require Solomon's wisdom and Einstein's insight. 44

Supp.)

4. The case scenario involving genetic testing of judicial competencies and predisposition is entitled Walker v. Judicial Nominating Commission. It may be ordered from from The Einstein Institute for Science, Health and the Courts, 5505 Connecticut Avenue, NW., Washington, DC

^{3.} Judicial temperament is a term of art generally incorporated into Canon 2 of the American Bar Association's Model Code of Judicial Conduct. A neuroscience-based conception of temperament may be found in Hamer, Living with Our Genes 12-25 (New York: Anchor Books/Doubleday, 1998); also see, Hamer, Tweaking the Genetics of Behavior, in "Your Bionic Future," 10 Scientific American 62-67 (Fall, 1999). This is a very different conception from judicial temperament highlighted in the legal literature that focuses mainly on intemperate behavior as a foundation for disciplining judges' misbehavior on the bench. See, A Perspective on "Temper in the Court," 23 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court," 25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court," 25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court," 25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court," 25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentificant of the court, "25 Fordham Urban L.J., 709 (1996); Decentific



No defined boundaries

by Dena S. Davis

The Clone Age: Adventures in the New World of Reproductive Technology, by Lori B. Andrews. Henry Holt and Co. 1999. 264 pages. \$25.00

If reproductive technology is the Wild West of medicine, as Lori Andrews claims, then Andrews herself is surely Paladin, the hero of "Have Gun, Will Travel." Whether she is jetting off to Dubai to advise the government on cloning; litigating a challenge to an Illinois law passed to deter in vitro fertilization; or brazening her way past the customs agent in Miami, straight off a flight from Columbia with a container of blood samples and sperm that "absolutely cannot" be opened, Andrews is in the thick of the action. This account of her adventures is a quick read and an enthralling story that should engage and reward the neophyte and sophisticate alike.

Any reader who begins this book with a dewy-eyed view of selfless doctors helping infertile women and men to have "miracle children" will soon be disabused. Andrews presents us with few heroes, and most of her characters are downright moneygrubbing, if not nefarious. Men come off much worse than women, but few people come off well. Her tale is largely one of carelessness, cynicism, and a focus on profit and scientific success for its own sake; the interests of the would-be parent or the baby it-

self are often so far in the background they hardly seem to surface at all. Andrews reminds us that it is harder to regulate reproductive technology than nuclear technology, and presents one "truism" learned from her career: "If it worked in just one animal, it will be tried in a woman."

Government employees appear no better than private researchers. Chapter 12, "Genetic Politics," is a particularly unflattering portrait of Francis Collins, head of the National Human Genome Research Institute-the folks who are spearheading the Human Genome Project together with the U.S. Department of Energy. According to Andrews, who took over from Nancy Wexler as chair of the working group set up to address difficult social issues such as genetic discrimination, the working group was deliberately torpedoed by Collins. After Andrews quit, she was told by James Watson, the famous geneticist and previous head of the Institute, that he had "wanted a group that would talk and talk and never get anything done."

As Andrews says, this book is primarily a memoir, and thus rather loosely organized. But simply by describing her own "adventures," Andrews touches on virtually all the interesting topics in reproductive technology. She describes the precipitous rise of multiple births engendered by infertility treatment, looks critically at the lack of concern for

the grave risks this poses to mothers and babies alike, and remarks that, "Like the proverbial traveling salesman who impregnates the farmer's daughter, the infertility doctors who use technology to create superpregnancies seem untroubled by their results." She takes us on a rather nauseating tour of websites and other venues created to sell upmarket sperm and eggs to wealthy buyers, and introduces us to a purveyor of sperm from Nobel prize-winners and other geniuses (only Mensa women need apply).

Abused and maltreated

Andrews reminds us of all the waysfrom negligence to deliberate malfeasance-that couples who use reproductive technology can be misused, abused, and maltreated. Sperm donation, for example, began in 1884 with a medical doctor inseminating a woman while she was anesthetized, without her knowledge or consent. A century later, Dr. Cecil Jacobson became mildly famous in Virginia for siring somewhere between 15 and 75 children with his own sperm, when he had told couples that he would be choosing sperm from anonymous donors matched to the husbands' characteristics. Worse yet, Jacobson gave some women hormones to convince them that they were pregnant, stringing then along for as much as 23 weeks with fake sonograms, only to tell them that they had "miscarried" and "absorbed" the babies into their bodies. Andrews points out that Jacobson was a respected clinician with a fine medical pedigree, and that, during his trial, many prominent people supported him and wrote letters on his behalf, including Senator Orrin Hatch.

Andrews' discussion of surrogacy is also filled with scary stories in which the children created through this process are in danger of being pulled apart by warring parents, or falling through the cracks with no parents at all. (Lawyers, it should be noted, are rarely more attractive than doctors in Andrews' universe.) Her chapter on posthumous reproduction, entitled

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"The Sperminator," is equally chilling in its portrait of reckless, self-serving doctors and grieving, impulsive families, rushing to "harvest" sperm from dead and comatose men without a firm notion of what those men would have wanted.

The most positive chapters in the book focus on genetic researchers doing fieldwork in Venezuela and Sardinia, two places with high concentrations of potentially lethal genes, in the first case for Huntington Disease and in the second for thalassemia. Andrews sketches some of the ethical ambiguities in this work, especially in Venezuela, where the research subjects lack the means even to obtain the basic medical care that we do know how to provide. She touches on some of the double standards that obtain between research in our own country and research with poor and uneducated people abroad. Nonetheless, the final portrait is of doctors and researchers honestly trying to help people faced with terrible tragedy, and of some actual good being done. In contrast, she is very wary of eugenic uses of genetic testing, and of increasingly more demanding "admissions standards" before children are welcomed into the world.

The book begins with the trip to Dubai, and the strangeness of that environment is Andrews' metaphor for her own work: no defined boundaries. And yet, Andrews does attempt to draw some lines. She begins and ends with the subject of human cloning, of which she disapproves. She worries that her largely successful legal efforts in the name of procreative liberty, on the part of women who wanted to use reproductive technology to conquer infertility, made her an unwitting champion of cloning as well. Perhaps she has done her work too well?

Roller-coaster of a read

This book is a great roller-coaster of a read, and one I will recommend to my law school library (and probably send to a couple of friends for Christmas). Andrews didn't write it as a sober treatise in ethics or law, and it would be wrong to compare it to her other work, which constitutes a large and impressive scholarly oevre. Nonetheless, precisely because this is the kind of work that will appeal to readers with little prior knowledge, I wish she had been a bit more careful to distinguish fact from opinion. For example, I disagree with Andrews' assertion that most (American?) scientists have now embraced the notion of human cloning, a shift that she said took "a matter of months." She may turn out to be right about this, but she doesn't present the evidence. I am more troubled by the way in which she sometimes presents hypothetical questions as if they were based on fact rather than speculation, a practice misleading to the unwary reader. (This habit may come

from constructing too many law school exams.) It would be easy to believe, from one paragraph in her "Genetic Politics" chapter, that a gene had been discovered and pinpointed that definitively predicted sexual orientation, and that the Armed Services was seriously contemplating using that gene to decide who to kick out of the army.

Although Andrews' galloping style makes the book so much fun, I wish she had spent a little more time drawing connections between the facts she presents and the inferences she draws. A particularly irritating example: "There is speculation that Dolly's cells most likely are set to the genetic clock of the nucleus donor and therefore are comparable to those of her six-year-old progenitor, which could psychologically lead people to view cloned animals and humans as short-lived, disposable copies." Well, I know that the first part of that statement is true, i.e., that the speculation about Dolly's "genetic age" exists. But who has been wondering if that early aging problem would lead people to think of cloned humans as disposable copies, and what are their grounds for their concern? That seems like an enormous and unwarranted leap, and I'd like to see some of the steps filled in. I'X

DENA S. DAVIS is an associate professor at Cleveland-Marshall College of Law.

Insecurity with science

by Michael B. Getty

Legal Alchemy: The Use and Misuse of Science in the Law, by David L. Faigman. W.H. Freeman and Company Publishers. 1999. 256 pages. \$24.95.

David L. Faigman's new book, Legal Alchemy, provides a thoughtprovoking review of the history of law and science. Beginning with their common roots in religion, Faigman contrasts religion's historical non-acceptance of science with the courts' sometimes total acceptance while failing to insist on validation. He points out that to understand the dichotomy between law and science one must realize that the prestige of the law is derived from adhering to traditions of the past, while the prestige of science turns on how quickly it can advance to the future. Even more pragmati-

cally, he suggests that science assumes behavior is based on biology and experience while the law assumes that humankind has free will. Faigman, a professor at Hastings College of Law, sees the law and science as rival siblings of mother religion.

This book is well written, thoroughly interesting and worthwhile reading for anyone. The author's periodic reference to law, classics, poetry, prose, as well as landmark cases, not only puts the subject in context but adds broad appeal. While the impetus for this work can

probably be ascribed to the Supreme Court's *Daubert* decision (which placed increased responsibility on judges to determine the reliability and value of scientific evidence), upon reflection it is clear that this treatise is both timely and necessary, regardless of *Daubert*.

Professor Faigman concludes that the Supreme Court, and courts generally, are reluctant to delve too deeply into scientific matters. This insecurity with science, however, has real costs—creating an assortment of doctrinal problems for the law. He posits that justices and judges do somersaults to avoid substantive specific analysis of science issues. His criticism, however, is not limited to the courts. He suggests:

- The courts' use of science has been slowed by the impurity of much of the science they see.
- Lawyers suffer from "syndromic lawyer syndrome," which he defines as acceptance of any simplistic explanation for complex human behavior that supports desirable legal outcomes.
- Politics often masquerades as science. For example, the rape trauma syndrome and the battered woman syndrome were offered as scientific fact but are really political ploys with little scientific support.

The Court and Congress

The author gives meaningful examples, from the Scopes trial to the O.J. Simpson case, and urges judges never to abdicate their responsibility for determining what is worthwhile

testimony. But perhaps his greatest criticism is reserved for the Supreme Court which, in the author's opinion, tends to interpret science data in light of accepted doctrine; he goes on to cite evidence of its disregard, misuse, and misunderstanding of such data. Faigman further points out that "the Court's ignorance of or disdain for science similarly leads to scholarly attempts to educate the justices, which in some measure influence their later decisions." This occurs, Faigman states, when justices misuse empirical research and become the subjects of significant criticism. For example, one of the justices, after being criticized for an earlier opinion, properly questioned the empirical significance of a flawed research study. Unfortunately, he then distanced his methodological critique, about which he was apparently not confident, from his constitutional analysis.

Faigman's treatment of Congress is somewhat more sympathetic. Congress, he opines, tends to set broad objectives and leaves to agency rule-making the more difficult task of science. He concludes that "Congress often bludgeons bureaucrats and scientists alike, sometimes for good reason. Most of the time, however, it swings wildly but without causing much harm."

Faigman believes that the real instrument of science policy in the United States is the bureaucracy of the executive branch of government. In his view, not funding worthwhile scientific institutions and projects is the Congress' principal failure, and his prime example was its failure to fund the Office of Technical Assessment, the agency responsible for advising it on scientific and technical issues.

Faigman discusses topical sciencerelated issues, from airbags to clean air to the wolf population in Yellowstone National Park. He describes the interaction regarding such issues of the executive branch (including the president and the administrative agencies), the two houses of Congress, and the trial and review courts of this country.

This book is a hybrid: part law school textbook of a most readable type, part personal editorial on how courts and Congress have, for the most part, failed on science and technical issues. He likens lawyers, judges, and policy makers who do not learn enough science to properly handle relevant issues to drug addicts who are satisfied with the status quo. As with treatment of addicts he recommends a 12-step program, the first step of which is to recognize the need for help. This is a book not to be missed by any judge, lawyer, or legislator who wants an informed understanding of the relationship between science and the law and how both can be made to serve society better.

MICHAEL B. GETTY, a former judge of the Circuit Court of Cook County, Illinois, is a mediator and arbitrator who chairs the ADR committee of the Einstein Institute for Science, Health and the Courts.

DNA's search for truth

by Clay Strange

And the Blood Cried Out: A Prosecutor's Spellbinding Account of the Power of DNA, by Harlan Levy. Basic Books. 1996. 224 pages. \$24.

And The Blood Cried Out is a readable account of the develop-

ment of DNA typing as the forensic tool of choice in the prosecution of violent crimes. It could easily serve as a textbook for lawyers and judges seeking a working understanding of DNA in the courtroom.

The title comes from the Bible

story of God's recognition that Cain had slain Abel, saying, "Hark, your brother's blood cries out to me from the ground." Such is a fitting connection to blood's (DNA) role in identifying modern murderers.

Harlan Levy, a former assistant district attorney in Manhattan, presents forensic DNA analysis through the prism of its usefulness in achieving justice by properly convicting guilty murderers and rapists who might otherwise escape prosecution. His considerable prosecutorial experience and knowledge of DNA enable him to tell the story in an interesting and non-scientifically intimidating manner. The book is filled with many satisfying passages about the search for the truth and pursuit of justice for the victims of heinous crimes.

Levy's explanation of why he was attracted to DNA as a specialty in prosecution is familiar. Very early on he saw its tremendous value in "promote [ing] a more just society, both by making punishment of the guilty more likely and by assuring exoneration of the innocent." He also came to realize, however, that although DNA was unparalleled in its determination of the truth, the truth wasn't necessarily a product the criminal courts were interested in. He became disillusioned with most judges' traditional view of trial "as a process, pursuant to the rules of evidence, to determine whether guilt has been proven beyond a reasonable doubt." This wish to preserve the process in many ways led to the famous DNA admissibility wars of the late 1980s and early 1990s.

The book's explanation of the basic biological concepts and the technologies employed to determine a genotype is concise, understandable, and not overly technical. Levy wisely chooses to not try to do too much teaching; rather, he succeeds by simply creating incentive for the reader to know more of the scientific process.

Examples of DNA use

The book begins with Levy's own introduction to DNA in the case known as the "East Side Slasher," which occurred in Manhattan. Levy prosecuted the pivotal DNA aspects of this case, the result of which was the conviction of a serial rapist turned murderer. There is a fascinating description of the techniques employed by the police in solving the crime and of the lawyers in presenting the evidence.

Levy gives a nice, though somewhat brief, description of the first

case in which DNA evidence was introduced. More fully described in Joseph Wambaugh's The Blooding, the case involved the serial murder of two English schoolgirls. Though of little importance to American criminal law, per se, the case remains one of the best examples of the promise of DNA in the promotion of justice for several reasons: 1) the DNA solution employed was not developed for forensic purposes [rather general human identification], 2) the analysis was performed by the father of DNA typing, Sir Alec Jeffreys, 3) the DNA result exonerated the first man arrested for the crime, 4) the investigation demonstrated the need for strict evidence controls [the actual perpetrator had a friend give a blood sample for him], 5) the solution was made possible by a somewhat coerced "voluntary" blooding [blood sample drawing] of 3,000 or so local men, and 6) the true perpetrator's name is one of first rank in the annals of crime-Colin Pitchfork.

One of the book's best stories concerns the case of Joseph Castro, whose name continues to both haunt and inspire forensic DNA analysis. Castro was charged in the Bronx in 1987 with the stabbing death of a young woman and her two-year-old daughter. The principal evidence was the probable blood of the victim on the watchband of Joseph Castro. Lifecodes, the first DNA laboratory in the U.S. to do RFLP testing, did DNA analysis and concluded the frequency of Castro's DNA type to be one in 100 million.

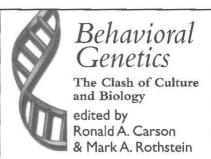
What followed was to be the only real derailment of an otherwise generally flawless progress toward widespread acceptance of and reliance on the reliability of DNA typing. Dr. Richard Roberts, an associate of James Watson, the Noble prize-winning co-discoverer of the double-helix structure of the DNA molecule, testified for the state. The defense countered with Dr. Eric Lander, an MIT scientist, among others, challenging the match criteria used by Lifecodes as well as other laboratory procedures.

After a lengthy, heated battle the trial court excluded the DNA evi-

dence (and Castro pleaded guilty, receiving a lesser sentence than if the DNA had been admitted). Levy's analysis of the *Castro* case is exactly correct: what had been widely accepted in the press and hailed as a major advance was now viewed skeptically, even as unreliable by one *New York Times* reporter. The fact that Castro was based "on technical aspects of a particular case and not the fundamental scientific validity of DNA technology" was obscured.

Levy chronicles the FBI's cautious entrance into the field of DNA analysis in 1989 and emphasizes the work of Bruce Budowle in bringing stringent scientific standards to the emerging field. It was that lack of standards and laboratory accountability that had caused much of the concern in the scientific community. A series of cases that followed turned the tide and DNA began to become widely accepted once again.

The most personal account in the book is also one of the most famous DNA cases: The Central Park Jogger



"At present we have an incomplete genetic inventory of the brain and hence of the consequences for brain assembly, homeostatic adaptation, ability and desire to learn, and whatever goes into resilience to internal and external stressors. Nevertheless, this ignorance is slowly being reduced, and the only clash I see is with those who would take the view that the rich biology of the brain is irrelevant to the causes of mental diseases, or to their cure or ultimate prevention . . . As this book amply demonstrates, there are many contrasting views and much data to be gathered if contrasting views of the causes of behavioral disorders are to be unified."-from the foreword by Floyd E. Bloom, M.D.

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Trial. The young woman was so viciously assaulted she was unable to identify the "wilding" attackers, but fortunately several of them confessed. One, Yasef Salaan, had given a self-serving "confession" and pleaded not guilty, but testified at his trial. His confession and testimony helped convict the other two defendants and his admission on cross-examination of possessing a pipe that night (the weapon used in the assault) helped convict him as well. The DNA evidence sample from the sexual assault examination kit had matched none of the defendants. To its credit, the Manhattan DA chose not to try to discredit the DNA result, but rather explained that at least one rapist was never identified and that the DNA profile yielded was most likely his.

DNA was to suffer one final setback. In 1992 the National Academy of Sciences National Research Council issued a report strongly endorsing DNA technology but which also created considerable confusion in the

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area of match probability. The report attempted a compromise known as the "ceiling principle," which sought to resolve perceived statistical difficulties within certain population subgroups. The proposed solution created a firestorm in the forensic DNA community. The FBI and most population geneticists attacked the concept as pure politics and bad science. The upshot was a second NRC report

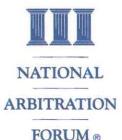
that discarded the "ceiling principle," re-instituted the statistical method previously used, albeit somewhat modified, and much more fully endorsed PCR as a valid forensic DNA typing method. The groundwork for such a favorable report had been set in 1994 in an article in *Nature*, co-authored by Bruce Budowle and Eric Lander. As former combatants, their joining in an article pro-

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claiming the end of the DNA wars became self-fulfilling.

DNA's value in exonerating incorrectly convicted defendants is not ignored in the book. Levy makes the important point that one of the values of DNA typing is that if the evidence were kept reasonably properly it may be tested accurately years later. Additionally, as most of us that have handled a post-conviction case can attest, no other evidence has the accuracy sufficient to overturn a jury verdict in the way DNA frequently has.

Levy's description of the O.J. Simpson case is wisely limited to an analysis of what DNA evidence was available, where it was found, what it was

used to prove, how it was presented, and how it was attacked. He very capably develops the twin defenses employed by the defense team: the planting of evidence by dishonest cops and laboratory contamination at the LAPD lab (through which all the evidence passed).

There had been grave concern in many parts of the forensic DNA community that a "not guilty" verdict in Simpson would damage DNA credibility in the manner of *Castro*. In fact, the actual analysis and testimony given by Robin Cotton of Cellmark Diagnostics and Gary Simms of California DOJ was outstanding. Indeed, the defense did not attack the integ-

rity of DNA typing itself, but rather successfully created doubt by raising questions of police misconduct and poor evidence handling. Moreover, one of Levy's final observations about the trial is shared by many prosecutors: there was too much DNA evidence available, which only added to the confusion created so capably by the defense.

Harlan Levy has given us a memorable description of the progress of DNA's remarkable contribution to criminal justice. I recommend it to any attorney or judge who might one day try a crime of violence.

CLAY STRANGE is an assistant district attorney in Travis County, Texas.

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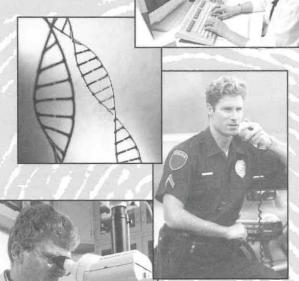
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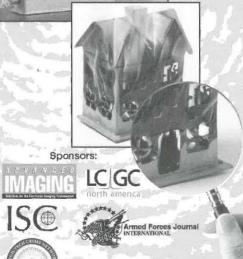
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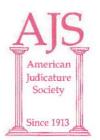


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