NLWJC - Kagan

DPC - Box 029 - Folder 015

Health - Medical Records, Privacy

Health- medical records privacy

long-term remediation. CERCLA allows remedial action only in the form of a judicial consent decree, the guidance said.

On the other hand, CERCLA orders are advantageous when the agency or the regional office seeks higher civil penalties. CERCLA 106 has a maximum penalty of $27,500 a day, whereas the maximum penalty per day under RCRA 7003 is $5,500. CERCLA orders also allow for punitive damages, whereas RCRA does not.

To avoid disputes over the timing and scope of judicial review, the EPA guidance suggests using CERCLA because it expressly prohibits pre-enforcement review. RCRA Section 7003 orders are not expressly protected, though EPA's view as stated in the guidance is that they also are not subject to pre-enforcement review.

A copy of the Guidance on the Use of Section 7003 of RCRA can be obtained for a charge from BNA Plus by calling 800-372-1033.

Health Care—Privacy

Administration's Privacy Proposal Needs To Be Strengthened, Witnesses Tell Senate

The Clinton Administration's proposal to Congress on medical records privacy legislation is inadequate in the areas of law enforcement access to information and federal preemption of state confidentiality requirements, a variety of witnesses told a Senate panel Oct. 28.

The Senate Labor and Human Resources Committee heard from congressional sponsors of privacy legislation, health plans, physicians, hospitals, pharmaceutical companies, and patient advocates.

Most witnesses said the administration's proposal, submitted Sept. 11 to Congress by Health and Human Services Secretary Donna Shalala (See 66 LW 2172), erred by allowing law enforcement officials too easy access to private medical information for health care fraud investigations by failing to require a court order or subpoena.

The administration's legislative recommendations were required by the 1996 Health Insurance Portability and Accountability Act. Congress has until August 1999 to enact privacy legislation, but HHS is required to adopt regulations for protecting the privacy of medical records transmitted electronically by early 2000 if lawmakers fail to act.

Uniform Rules Important. John Glaser, a principal author of the National Research Council report, *For the Record: Protecting Electronic Health Information*, told the Senate panel that federal statutory law should override state medical records privacy protections. He called it important to have uniform regulations, laws, stiff penalties, and more constraints on types of information that are more sensitive than others. Part of the NRC report is expected to be included in soon-to-be-issued HHS proposed regulations to protect the security of medical data transmitted electronically.

In addition, Glaser urged the panel not to pursue a unique patient identifier for use in an electronic health care transaction system until the privacy protections are in place. While there is value to the use of such a device, it raises real concerns without national protections in place, he said. Few technical barriers exist to implementing security practices, he told the panel.

Preemption of State Laws. Several witnesses agreed that because the health care system routinely constitutes interstate commerce, federal legislation should preempt state laws to avoid confusing and costly requirements on providers and plans.

John Nielson, representing the American Association of Health Plans, said the group takes the position that any preemption provision in federal legislation should not affect state public health laws, but strongly recommends that a federal law address the need for nationally consistent rules in areas that affect computerized information systems. Multistate health plans and employers will have great difficulty complying with varying federal and state standards if rules governing the disclosure of computerized health records differ from state to state, he said.

Nielson called it critically important that legislation allow health plans to engage in activities related to health promotion and disease management, quality assurance improvement and related research, and utilization review without separate patient information disclosure authorizations.

But a patient advocate, A.G. Breitenstein, an attorney with the Health Law Institute, said the administration's proposal fell short of giving patients more control over their own information by destroying the concept of voluntary informed consent.

Witnesses generally said that without some kind of federal privacy protections for personal medical information, patients could suffer, in part because patients may withhold information from their medical providers, avoid treatment, or fail to participate in the kinds of research that would lead to valuable medical discoveries.

American Medical Association board member Donald Palmisano said he was troubled that the administration's proposal assumes patient consent in several situations. Where there are conflicts over the right to privacy, the resolutions should side with the patient except when others would be harmed, he said.

Current Legislative Proposals. Sen. Patrick Leahy (D-Vt) Nov. 4 introduced a bill (1368) that would give individuals the right to govern the access to their personal medical records in several ways. These include viewing their own records, paying for medical care themselves if they want to prevent personal health information from being disclosed to a health insurer, and segregating parts of the medical records such as mental health treatment records from the view of people not directly involved in their health care.

Leahy's bill, which would not preempt stronger state laws, is supported by the American Psychiatric Association. Leahy and others noted that all civil rights laws generally allow stronger state protections to co-exist with the federal statute.

Sen. Bob Bennett (R-Utah), who co-sponsored in the 104th Congress with Leahy a measure similar to Leahy's new bill, said he would introduce a separate measure in 1998. He called on the 105th Congress to bring the matter to a close and act on privacy legislation.

Bennett said his draft bill parallels the administration's proposal to a large extent; it differs, however, on law enforcement and state preemption. He suggested

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Health-Medical records-privacy

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URGENT

TO: Elena Kagan, Deputy Assistant to the President for Domestic Policy
Fax No. (202) 456 2878

Christopher C. Jennings, Deputy Assistant to the President for Health Policy
Fax No.: (202) 456 7431

cc. Robert S. Litt, DAAG
Fax No.: (202) 514 6034

FROM: Ian C. Smith DeWaal,
Voice: 202-514-0669 ICSD

SUBJECT: Attached Language

DATE: September 30, 1997

COMMENT: Per the request of DAAG Litt, I am faxing the attached.

TOTAL PAGES TRANSMITTED (including cover sheet): 2

We support language which would make clear that the derivative use of health information disclosed to oversight or law enforcement agencies is subject to the same limits imposed on the initial use of that information by those agencies. This is consistent with current practice and has always been our understanding of the import of the recommendations made by the Secretary of Health and Human Services. We would therefore support clarifying language in those recommendations as follows:

"After health information has been disclosed to an oversight or law enforcement agency engaged in an oversight or law enforcement activity, the further use or disclosure of that health information shall be limited to legitimate oversight and law enforcement activities, except as otherwise permitted by these recommendations."

In addition, with the "Right to Financial Privacy Act" as a model, we would support the destruction or return of the medical records, once the oversight or law enforcement need for them has expired. We would support adding the following language to the Secretary's recommendations:

"Once the law enforcement or oversight activity for which a medical record was disclosed has finally concluded, or if the medical record was further disclosed or used for a subsequent law enforcement or oversight activity, once the subsequent activity is finally concluded, the medical record and any description of its contents shall either be destroyed or returned to the source from which it was originally obtained, except for the sealed records of a grand jury, or where retention is ordered by a court of competent jurisdiction, or where retention is otherwise required by law."

Health- medical records, privacy

9-30-97. Med Records Privacy.

Decision not to change status quo re law enf. access to med records.

NYT article - surprised we empowered law enf to go beyond what they can do today.

(Need to enlist help of AG to push back a bit.)

(Litt: working on op-eds)

One issue has come up - redisclosure of materials by law enf.

Litt: We drafted letter to deal w/ issue. Now transmitted to OIRA. (copies to Chris + me.)

You're right - this was always our understanding.

Harder issue -

law enforcement and overright activities

?? → what is the difference? } administrative/civil

can be used for other purposes?

Litt: a law enf officer who legitimately comes across ev of crime shouldn't ignore it.

in every agency of law this is true.

Klaxon: W/out cr process - access to many other people's private info.

Health-med records, privacy

Q: HOW DO YOU RESPOND TO ROBERT PEAR'S STORY WHICH SAYS THAT THE PRIVACY PROTECTIONS BROADEN ACCESS OF POLICE TO MEDICAL RECORDS?

A: First of all, it is simply not true that the privacy recommendations the Secretary will discuss tomorrow will broaden access to medical records to law enforcement officials. In fact, the report states that:

"We are not recommending any changes to existing legal constraints that govern access to or use of patient information by law enforcement agencies. In getting information law enforcement officials should have to comply with whatever other law was applicable. Therefore, if state law permitted disclosuure only after compulsory process with court review, a provider or payer should not be allowed to disclose information unless the law enforcement authorities had complied with that requirement."

In fact, the recommendations to protect privacy strengthen the penalities for all those who disclosure medical records inappropriately. As it states: "our recommendations would make obtaining health information under false pretenses to be a Federal felony."

The privacy report the Secretary of HHS will discuss tomorrow will recommend strong new protections including new restrictions on providers, payers and others who create and receive health care information. It also provides consumers with significant new rights to be informed about how their health information is used. However, while we are recommending strong new privacy protections, we do not choose to undermine law enforcement's current legal authority to investigate a crime or identify a victim.

Health - med records, privacy

Date: 09/10/97 Time: 08:53
HPolice would get unfettered access to medical records

WASHINGTON (AP) The Clinton administration wants law enforcement officials to continue having full access to patient medial records.

No federal laws restrict access to and the disclosure of patient medical records now, but several bills have been introduced in Congress to provide them as such information is becoming increasingly available through computer networks.

The administration recommendation to be made to Congress this week comes as the Department of Health and Human Services attempts to balance privacy concerns with the need to investigate fraud and abuse in both government and private health insurance programs.

HHS Secretary Donna Shalala will testify to a Senate committee Thursday on the department's recommendations.

After a review, HHS concluded that law enforcement should continue to enjoy access to health to investigate fraud and other crimes without first getting patients' permission, Melissa Skolfield, an HHS spokeswoman, said Tuesday night.

But she said the department will recommend new punishments for those who misuse health data.

Skolfield said the recommendations also would continue to allow unfettered access to academic researchers, who rely on patient information to study trends and diseases.

Shalala said last month that a national system is needed to replace a patchwork of state laws governing privacy of health records.

''The way we protect the privacy of our medical records is very erratic, and it's dangerous,'' she said.

At the time, she said she would propose the following recommendations to Congress:

Prohibit use of personal information for anything other than health care, and punish those who misuse it.

Require data keepers to keep the information secure.

Allow consumers to see what is in their health records and give them a way to change incorrect data.

APNP-09-10-97 0854EDT

Health-med records Privacy

Bruce/Chris/Jose —
FYI.
Elena

U. S. Department of Justice

Office of Intergovernmental Affairs

Office of the Director

Washington, D.C. 20530

August 20, 1997

MEMORANDUM FOR: Elena Kagan
Deputy Assistant to the President and
Deputy Director of Domestic Policy

FROM: Nicholas M. Gess
Director of Intergovernmental Affairs
Department of Justice

SUBJECT: Medical Records Privacy

Pursuant to our conversation this morning, I am enclosing a copy of a draft white paper which has been prepared by the Justice Department's Criminal Division regarding law enforcement access to medical records. The white paper is an outstanding summary of the concerns raised by any legislative proposal, report or other statement of Administration position which do not include an appropriate law enforcement exception.

The current Administration position is that any medical records privacy legislation ought to contain a law enforcement exception. This was decided after the matter could not be resolved by OMB or the agency principals (the Attorney General and the Secretary of HHS). The matter was ultimately decided by the Chief of Staff Leon Panetta. Any change will represent a change in Administration position.

The National Association of Attorneys General and the National District Attorneys Association have huge concerns here and have previously expressed those to the President, the Attorney General and other senior Administration officials, both privately and publicly. I also know, from my own discussions with them, that both the International Association of Chiefs of Police (IACP) and the National Sheriffs Association (NSA) favor a law enforcement exception as well.

We want to work with HHS and avoid any last-minute or hurried consideration. The Department's lead on this issue is Bob Litt (514-2636) and I will be working on this issue as well.

Please feel free to call me if we can provide any further information. Many thanks in advance for your help.

Enclosure

DRAFT

Law Enforcement Access to Medical Records

The issue of law enforcement access to and use of information contained in medical records has been the subject of much historical debate. The growth of the private and public health care insurance plans with a parallet growth in health care fraud investigationshas significantly increased law enforcement use of medical records. The need for law enforcement access to health records to investigate and root out pervasive health care fraud which is draining the resources of both government and private health insurance programs is compelling. Further, patients participating in these programs routinely agree to the disclosure of their medical records to document their treatment as a condition of receiving reimbursement for their health care costs. In fact, without the ability of law enforcement to access and use patient medical records, our health care fraud efforts would collapse.

Likewise, medical records may also contain important evidence of crimes not involving health care fraud. Law enforcement agencies have traditionally been able to obtain such records through judicial or administrative compulsory process, or through voluntary disclosure by health providers of limited health information in emergency situations, such as a kidnapping, a search for an injured, but armed assailant, or a search for a fugitive. The privacy of medical records disclosed to law enforcement are protected by grand jury secrecy requirements, Privacy Act requirements, administrative regulations, and the important interest of law enforcement in maintaining the confidentiality of investigations.

No evidence has been presented which demonstrates that law enforcement agencies engage in widespread abuse of medical information in non-health care matters. The National Committee on Vital and Health Statistics ("NCVHS") conducted six full days of hearings as a prelude to this report. A number of representatives of the federal and state law enforcement community testified about law enforcement's excellent track record in accessing and using medical records. No contradictory evidence was presented to the NCVHS.

The law enforcement community argued convincingly that new, burdensome and costly restrictions on legitimate law enforcement activities should not be imposed without some evidence of widespread abuse by the law enforcement community. Law enforcement witnesses testified that the imposition of new restrictions and procedures would divert investigative resources, impede and delay legitimate law enforcement activities, and even lead to the termination of otherwise legitimate investigations. State and local law enforcement representatives testified that medical record evidence could be critically important in a number of cases such as kidnapping, murder, assault, rape and locating fugitives.

DRAFT

The fact of the matter is that by far, the vast majority of disclosures of health information to law enforcement occurs in the context of health care fraud investigations. Carving out for enhanced protection, the comparably small subset of disclosures to law enforcement which occur in the context of non-health care investigations, will not provide any meaningful new or widespread privacy protection to patients. In contrast, demonstrable and substantial burdens and costs would be imposed on law enforcement.

Some privacy advocates have expressed a willingness to exempt investigations of a limited number of violent crimes from new medical record privacy legislation. While this addresses some law enforcement concerns, the resulting patchwork of varying standards would force the judiciary into second-guessing which legislative determinations criminalizing specific behavior should be enforced and which should not. The inevitable inconsistent judicial determinations of which crimes warrant the disclosure of medical records and which do not, would inject new and unwarranted arbitrariness in the enforcement of federal and state laws.

Under current law, law enforcement does not presently exercise unfettered access to health information. Current practice requires generally, except in emergency situations, that law enforcement obtain compulsory process to obtain medical records. Information produced pursuant to a grand jury subpoena is subject to strict secrecy requirements. Search warrants are approved by judicial authorities only on a showing of probably cause that a crime has occurred and a likelihood that the items specified in the search warrant, which could include medical records, will contain evidence of that crime. Administrative subpoenas cannot be issued without meeting statutory and regulatory requirements as well. Also, existing statutes and regulations protect the societal interest in reducing drug abuse by promotion of treatment programs, which would likely be deterred across the board if participating patients could be prosecuted for violating drug laws. Finally, judicial decisions have also generally provided enhanced protection for sensitive mental health records.

The Administration carefully considered and reviewed these arguments in the context of proposed S.1360, the "Medical Records Confidentiality Act of 1995." In the absence of documented abuse by law enforcement, the Administration was extremely reluctant to impose expensive new restrictions on the federal and state law enforcement communities which could substantially impede legitimate law enforcement investigations.

Furthermore, exempting law enforcement from health information privacy legislation would not expand or enhance existing law enforcement access to health care information, but would merely maintain the status quo. Law enforcement would still be subject to existing statutes, court decisions, procedures and policies with respect to obtaining health

DRAFT

information and maintaining its privacy. Consequently, the Administration determined to support a law enforcement exemption from pending medical record privacy legislation and communicated this position to Congress in April, 1996.

In the ensuing review of this issue which preceded this report, including the hearings conducted by the NCVHS, no new evidence emerged of law enforcement misconduct with respect to medical records. In the absence of such evidence, there simply is no current justification to impose new burdensome and costly restrictions on law enforcement. Therefore, the Administration affirms its previous position and urges that law enforcement be exempted from any new medical record privacy legislation.

Health - medical records privacy

8-18-97 Telecon w/ Nick Gess

Medical Records Privacy -

Arose last yr. Dispute btw DOT and HHS. DOT won.

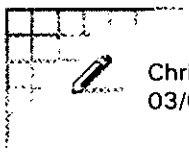
Decision to have law enf exceptn.

Only Thing That passed - com'n to report back.

Report date Aug 21.

Com'n going to say there needs to be blanket med rec. priv stat w/out law enf exceptn.

Health-Med Records
Privacy



Christopher C. Jennings
03/08/97 05:51:07 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP
Subject: Re: Ideas to vet

Good timing on the privacy issue. We are planning on holding a meeting with HHS, OMB and perhaps others on this issue hopefully sometime next week. Items like genetic screening info, as well as medical records protections will come up. This was an issue that got largely dropped in the Kassebaum-Kennedy bill last year because of a lot of controversy and bickering with the business, insurer and consumer communty. The provision that got included was a directive that HHS come up with regs within, I think, two years but only if Congress had not passed something in the interim. While we could certainly include this in the Commission's charge, we may also want to see if we could develop something independent of the Commission (so as not have it drag on.) I'll give you a complete update after our meeting. I think it might be very good if Elena had the time to sit on this issue -- if she is interested. There are a lot of legal angles here that would benefit from her participation.

Re the criminal checks, as you mentioned in your note, we just did that on the home care reg. We may want to extend it to other health care providers as well. I will see how much more juice we can squeeze from this issue...

cj

Re

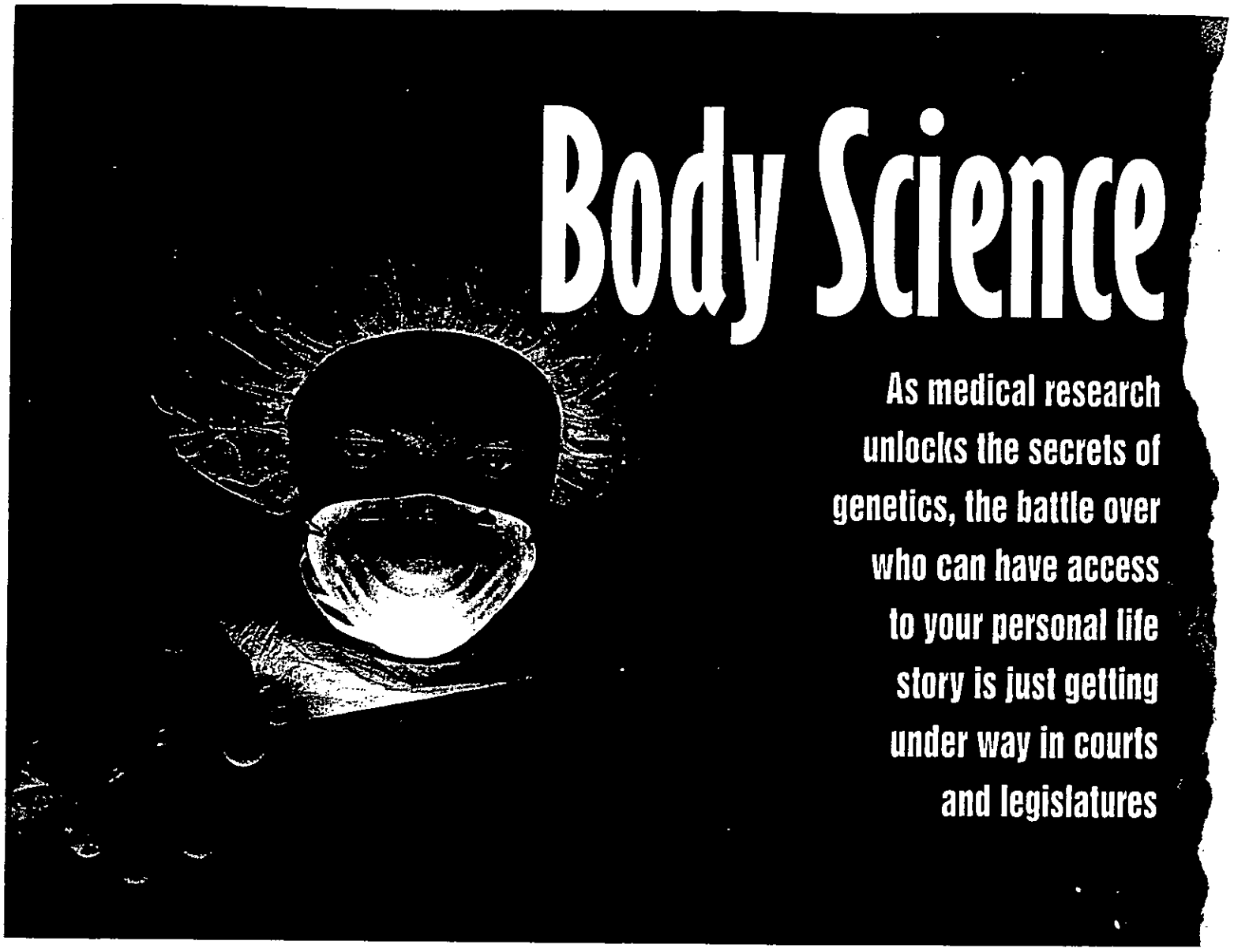
April 5, 1997

NOTE TO BRUCE REED, ELENA KAGAN, CHRIS JENNINGS, and ELIZABETH DRYE--

Attached is an interesting cover story on genetic testing from the most recent issue of the ABA Journal. This is way out of my bailiwick, but I was surprised to learn that insurers had so much leeway to tailor or refuse coverage based on genetic testing. I know that the question of pre-existing conditions has always been a tough one, but at first blush this seems awfully problematic, as does the possibility that someone might not take a possibly valuable genetic test for fear of insurance consequences. The article made me wonder whether we are doing anything on this front....

-- Bill Kincaid

File: Health - Privacy



Body Science

As medical research unlocks the secrets of genetics, the battle over who can have access to your personal life story is just getting under way in courts and legislatures

BY LORI ANDREWS

Predicting the future always has been a human temptation. In one very important sense, we now are close to being blessed—or cursed—with getting our wish.

At an increasingly rapid pace, biological scientists are using genetics research to develop ways for us to learn more about ourselves—more, in fact, than we might ever want to know.

"We used to think our fate is in our stars," observes James D. Watson, who helped unlock the secrets of DNA in the early 1950s and now directs the Laboratory of Quantitative Biology, a major genetics research center at Cold Spring Harbor on Long Island in New York. "Now we know, in large measure, our fate is in our genes."

Strung together in the almost mystical double helix form of DNA, genes are the basic unit of heredity. They are contained in chromosomes carried by every cell in our bodies. Each cell contains DNA carrying the entire human genome, or all the genetic information necessary to build a person.

Because each human's genes are unique, they are a personal map for that person's biological past and future—the traits inherited from parents and the ones to be passed on to children.

Unfortunately, not all the genetic news is good. As scientists learn how to "read" genes, they can predict a growing list of potentially harmful diseases and traits.

The bad news contained in genetic information holds deeply personal implications for each individual, but it also is the reason why third parties, such as insurers, employers, schools, the military and the courts, increasingly want to be in on the secret.

The debate over who should have access to genetic information about individuals is likely to intensify in the near future as the pace of discovery picks up in the genetics

Lori Andrews is a professor at Chicago-Kent College of Law and a senior research fellow at the American Bar Foundation. She is the recipient of a grant from the National Center for Human Genome Research of the National Institutes of Health to develop a policy framework for genetic technologies.

TONY STONE IMAGES/MARK JOSEPH

A medical technician studies DNA sequences. Genetic testing, once limited to detection of rare diseases, is in the works for heart disease, diabetes and cancer.

field. Courts and legislators are sure to be at the center of the controversy.

Much of the spark for that explosion of knowledge about genetics comes from the Human Genome Project, co-directed by the National Institutes of Health and the Department of Energy. In the project, the federal government is spending some $3 billion to support efforts to catalog the entire human genetic blueprint by 2005.

For 20 years, genetic testing has been performed on fetuses. One of the first predictive tests for healthy adults screens for the gene that causes Huntington's disease, a debilitating, fatal neurological disorder. Young, healthy people who test positive for the inherited Huntington's mutation know it will kill them someday.

Such genetic news can be psychologically devastating. Consequently, fewer than 14 percent of people at risk for Huntington's disease decide to undergo the genetic testing that may force them to confront their medical future.

But genetic testing is no longer limited to relatively rare diseases such as Huntington's.

Similar tests are being developed for more common disorders such as heart disease, diabetes and certain cancers. Genetic testing also is being proposed for numerous behavioral disorders such as alcoholism, manic-depression and even "risk-taking" behavior.

People are starting to use genetic information to measure the consequences of major life decisions: where to live, what job to take, what type of insurance to purchase, even whether to bear a child.

No Easy Decision

Deciding whether to undergo genetic testing is not easy.

Women with a strong family history of breast cancer, for instance, are faced with the prospect of learning, through testing, that they inherited a genetic mutation that poses an 80 percent lifetime risk of the disease. But if genetic testing does reveal the breast cancer gene, the woman risks losing the health insurance she may need so badly later on.

"These are not just hypothetical fears," says Nancy Wexler, a clinical psychologist at Columbia University in New York City who has studied families that carry inherited disease. "People who are using genetic testing are losing their insurance. And other people who should avail themselves of genetic testing are losing their lives to save their insurance."

Wexler has a personal stake in her own research. As a member of a team in Venezuela that identified the specific gene for Huntington's disease in 1993, Wexler was zeroing in on what someday may kill her. The disease killed her mother, and Wexler is at 50 percent risk of developing it as well. She has testified before Congress about her belief that people have a right not to know their genetic makeup.

Such decisions about whether to undergo genetic testing are at the heart of the growing legal debate over genetic predictability. Individuals at risk fear that test results may be used against them by employers, insurers, school officials, courts, mortgage lenders, adoption agencies, the military and other entities. At the same time, those institutions claim that individuals are not entitled to deprive them of information that could impact the institutions' own interests.

Genetics is not totally new to the courts—just ask the juries in the O.J. Simpson trials who heard reams of testimony on DNA typing of blood samples. Similar tests also are common in rape and paternity cases.

But those types of cases use genetic factors to link accused parties to incidents that occurred in the past. In the new realm of genetics, the issues are prospective: Do people have a privacy right to their genetic information, or do other parties have a right to demand that it be revealed?

Those questions are arising in a growing number of legal settings: medical malpractice, employment, education, family and civil rights.

Few laws protect intrusions on genetic privacy despite the personal nature of the information.

"The highly personal nature of the information contained in DNA can be illustrated by thinking of DNA as containing an individual's 'future diary,' " says George Annas, a health law professor at Boston University. "A diary is perhaps the most personal and private document a person can create. Diaries describe the past. The information in one's genetic code can be thought of as a coded probabilistic future diary because it describes an important part of a unique and personal future."

In addition to concerns about privacy, institutional interest in an individual's genetic information raises fearsome ghosts in a century that has witnessed far too many waves of genocide, forced sterilization and stigmatization of entire groups of people on the basis of their supposed genetic inferiority.

Moreover, there are concerns that human genetic materials may come to be viewed as commercial products.

"Blood, tissue, placenta, cell

Genetics Basics

Unwinding the human genetics code begins with:

A cell—Each of 100 trillion in the human body (except red blood cells) contains all the genetic information necessary to create a human being. This information is encoded in 6 billion base pairs, or subunits of DNA.

The cell nucleus—Six feet of DNA are packaged into 23 pairs of chromosomes inside the nucleus (one chromosome in each pair comes from each parent).

A chromosome—Each of the 46 chromosomes contains the DNA for thousands of individual genes, the units of heredity.

A gene—Each gene is a segment of double-stranded DNA that holds the formula for a specific molecule, usually a protein. These formulas are spelled out in varying sequences of the four chemical bases in DNA that can fit together only in a specific way.

Reprinted from *Blazing a Genetic Trail* © 1991, Howard Hughes Medical Institute

Illustrations by Wood Ronsaville Harlin Inc. for Howard Hughes Medical Institute, *Blazing a Genetic Trail* © 1991

A federal court ruled that two Marines, Cpl. Joseph Vlacovsky and Lance Cpl. John Mayfield III (shown with attorney Eric Seitz) did not have the right to refuse military DNA testing.

lines and genes are valuable resources in the age of biotechnology, useful as sources of information and raw material for commercial products," says Dorothy Nelkin, a New York University sociologist and coauthor of *The DNA Mystique: The Gene as a Cultural Icon.* "Geneticists rely on routine access to body tissues for their research. And some biopsied tissue has acquired commercial value as a source of raw material for the development of pharmaceutical products."

Despite these concerns, the law generally has upheld third-party access to a person's genetic information on a number of fronts.

Marines on the Genetic Frontline

On Dec. 16, 1991, the deputy secretary of the U.S. Department of Defense quietly issued an obscure memo that opened the largest DNA bank in the world.

The directive required that every member of the U.S. armed forces and all new recruits provide the Armed Forces Institute of Pathology with a DNA sample, which would be maintained on file for 75 years.

The goal of this ongoing program is to obtain specimens for all active and reserve personnel by 2001 for a very simple reason: to make it easier to identify battlefield dead.

In January 1995, two members of the Marine Corps, Lance Cpl. John C. Mayfield III and Cpl. Joseph Vlacovsky, reported for what they expected to be a routine physical. But when they were informed that they were to provide blood and saliva for DNA sampling, they refused.

The two Marines agreed that using DNA to identify remains was benign, but they expressed concern that the military could, at some point in the future, use the DNA samples for some less innocuous purpose, such as the diagnosis of hereditary disease or disorders, and then could disseminate such information.

Mayfield and Vlacovsky were court-martialed for refusing to obey an order from an officer. In subsequent proceedings, the Marines asserted that the collection, storage and use of their DNA violated their rights to freedom of expression, privacy and due process under the U.S. Constitution.

Their strongest argument was that unreasonable searches and seizures are prohibited by the Fourth Amendment—the same provision that protects a criminal defendant, for example, from being subjected to stomach pumping when police see the suspect swallow a bag of cocaine in efforts to destroy evidence.

In September 1995, a federal court ruled in favor of the government in *Mayfield v. Dalton*, 901 F. Supp. 300, holding that its interest in accounting for the fate of soldiers and assuring peace of mind to next of kin overrode the constitutional interest of individual service personnel in being free from searches and seizures.

The ruling allowed the military to court-martial the Marines, but they ended up getting light sentences: a reprimand and seven days' restriction to base. The military's policy of requiring DNA testing of its members has not changed.

Members of the military are not the only people in this country with DNA profiles on record. Some insurance companies are requiring genetic testing as a condition of coverage, and others are dropping insureds or charging them higher rates on the basis of genetic information discovered through other channels.

In one instance, a pregnant woman whose fetus was affected

Framing the Debate

As courts, legislators and other policymakers approach the difficult issues surrounding advances in the science of genetics, they might consider a three-prong policy framework:

- First, legislation, court decisions and other expressions of policy should assure that people have control over what genetic information is generated about them. Legislation in New Hampshire makes this point, for instance, by stating that, except with respect to paternity testing, newborn screening and forensic testing, "no genetic testing shall be done without the prior written and informed consent of the individual to be tested."
- Second, individuals should have control over who has access to their genetic information.

AP PHOTO/HONOLULU STAR BULLETIN, KEN IGE

when she underwent cystic fibrosis testing was informed by her insurance company that it would not pay for the child's health care costs if she chose to complete the pregnancy.

In another case, a woman whose mother had breast cancer was told her own health care coverage would exclude treatment of breast cancer. Even some people who participated in genetics research have subsequently lost their health insurance, including a man who underwent screening for a type of colon cancer as part of a study at the Huntsman Cancer Center at the University of Utah.

Basing Insurance on Genetics

These actions do follow a certain calculated logic. Since it is accepted policy for health insurers to exclude people with pre-existing disorders, genetic testing provides an enormous loophole for classifying numerous diseases or other medical conditions as pre-existing because they have their roots in the genes of prospective insureds.

At first glance, such a policy might seem reasonable, akin to charging smokers higher rates. After all, insurance is based on the concepts of risk-spreading and risk-sharing. When most people's future health risks are unknown, the future health care costs of a group can be predicted on an aggregate, actuarial basis and the costs spread across the whole group.

But with genetics technology beginning to identify which people in a group are likely to develop particular diseases later on, insurance companies have begun to target them for special treatment: higher rates or denial of coverage.

Carried to its extreme, that approach to coverage could make everyone uninsurable, since every human being carries between eight and 12 "defective" genes that might trigger various medical disorders.

Moreover, the insurance industry's developing policies on genetic predictability raise the same privacy concerns for insureds raised by the two young Marines in the face of the military's mandatory DNA screening policy. Many people do not want to be forced to gaze into their biological crystal balls.

In some states, legislators have begun passing bills to prohibit discrimination by insurers based on genetic information.

But the laws passed so far may be too narrow. In Wisconsin, for instance, the legislative protection against insurance discrimination applies only to DNA tests and does not cover tests that analyze proteins contained in genes or information on family histories.

In North Carolina, the law protects only people who carry the gene for sickle-cell anemia (which strikes blacks and, to a lesser extent, some Europeans of Mediterranean descent).

As early as 1989, according to a survey of employers by the congressional Office of Technology Assessment, one in 20 companies conducted genetic screening or monitoring of workers.

And even if employers themselves do not undertake genetic testing, they may receive such information about their employees in other ways. It might be found in medical records submitted by an employee in support of a health insurance claim or reported by the employee's doctor.

"Physicians are increasingly being put into the role of 'double agents,' with dual loyalties to the patient and to the patient's school, employer, potential insurer, relative or child," observes sociologist Nelkin.

Genetic testing by employers has been accompanied by discrimination based on that information.

In the early 1970s, a number of companies discriminated against black employees and job applicants who carried sickle-cell anemia even though that status had no bearing on an employee's current or future health, or on an employee's ability to work since the only significance of carrying the trait was a 1-in-4 chance of passing the disease on to a child if the other parent also was a carrier.

Yet few states have laws banning genetic discrimination in employment. Only six—Florida, Georgia, New Hampshire, New Jersey, New York and Oregon—have statutes explicitly prohibiting genetic testing without consent.

At the federal level, the Americans with Disabilities Act provides some protection against job discrimination for people who carry genes that predispose them to diseases later in life.

The compliance manual of the Equal Employment Opportunity Commission states that under the ADA an employer may not discriminate against a person based on genetic information relating to illness, disease or other disorders. The EEOC indicated, for example, that an employer may not refuse to hire someone just because his or her genetic profile reveals an increased susceptibility to colon cancer.

But the ADA still permits employers to order genetic testing of people who have been offered employment, even without their permission, as long as the information is not used in unfair ways.

This can be accomplished through measures that expand upon state medical confidentiality laws. A statute in Colorado states, "Genetic information is the unique property of the individual to whom the information pertains. Information derived from genetic testing shall be confidential and privileged. Any release, for purposes other than diagnosis, treatment, or therapy, of genetic testing information that identifies the person tested with the test results released requires specific written consent by the person tested."

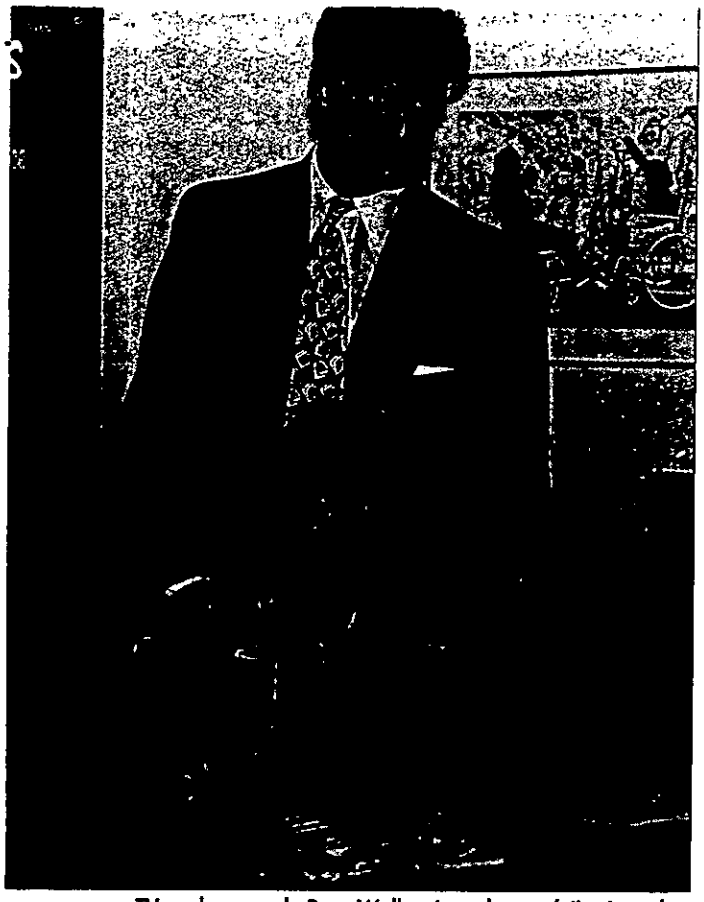
Moreover, those generating or collecting genetic information should explain their confidentiality protections in advance of delivering those services.

Third, discrimination against individuals based on genetic information should be prohibited.

Seven states have laws prohibiting employers from using genetic information to discriminate: Iowa, New Hampshire, New Jersey, New York, Oregon, Rhode Island and Wisconsin. And seven states prohibit insurers from requiring or requesting genetic tests: Georgia, Maryland, Minnesota, New Hampshire, New Jersey, Ohio and Wisconsin.

Nine states prohibit insurers from using information derived from genetic testing to deny coverage or to limit the terms and conditions of insurance: Colorado, Georgia, Maryland, Minnesota, New Hampshire, New Jersey, Ohio, Oregon and Virginia. (The health insurance laws are a hollow victory, though, since they do not apply to self-insured plans, which are used by most large companies.)

—*Lori Andrews*



TV anchor-couple Bree Walker Lampley and Jim Lampley were excoriated for conceiving in light of her disability.

In September 1995, the San Francisco Legal Aid Office filed a class action lawsuit by employees of Lawrence Berkeley Laboratories, a research center at the University of California at Berkeley that receives funding from the U.S. Department of Energy.

The suit, *Norman-Bloodsaw v. Lawrence Berkeley National Laboratories*, No. C95-03220 (N.D. Cal., filed Sept. 12, 1995), alleged that the lab had tested black employees for the sickle-cell gene without their knowledge or consent, and had secretly maintained that information in employee files.

The suit was dismissed on grounds that the secret testing did not constitute an intrusion on employee privacy.

Reading, Writing and Genetic Testing

In U.S. schools, genetics is more than just a subject for science classes.

In a few places, schools are using genetic tests to screen students for a syndrome that identifies borderline retardation. In the future, schoolchildren might be screened to identify genes for dyslexia or other learning difficulties, then receive special assistance to compensate for the genetic flaw.

The problem with such an approach, however, is that even if such genes can be identified (and this is a big "if," given that reputable researchers from respected institutions such as Yale have in recent years claimed to have found genes for complex behaviors only to later have to retract their findings), carrying a gene and manifesting the disorder are two different matters.

Not all genes are completely penetrant; there are many genetic conditions that occur in only a minority of the people carrying the gene. Often the gene indicates only a predisposition to a disorder that needs additional intervention, such as a particular environmental exposure, to be triggered. This means some children may be labeled as deficient because they carry a gene rather than manifest a condition.

The implications are profound. The work of social psychologist Claude Steele at Stanford University indicates that students perform more poorly if they know they are members of a group that traditionally has not been academically strong, a phenomenon known as "stereotype vulnerability."

Teachers' perceptions of students might be affected by such genetic stereotyping, giving lower grades to children identified as having an errant gene even if they are performing normally. That pattern has been identified in psychological studies in which teachers were told that one group of students was better than another when there actually was no difference. The teachers gave the "better" students higher grades and more attention, presumably due to the "halo" effect of a positive label.

The use of genetic screening in higher education is even more problematic. In one case, a man who was at 50 percent risk for Huntington's disease was rejected by medical schools on grounds that it would be a waste of money to train someone who might die young.

For judges with a full load of complex cases, the idea that genetic information might provide some guidance is seductive. Consequently, the use of genetic testing to answer an expanding variety of legal questions is growing, often without sufficient thought to the social context or impact.

In a recent case in Charleston County, S.C., a judge ordered that a woman be genetically tested for Huntington's disease at the instigation of her ex-husband, who was seeking to terminate her parental rights.

This type of case may foreshadow a new kind of battle in custody cases, in which the divorcing parents seek genetic testing on each other to determine who is more predisposed to die sooner from cancer or heart disease. Under this approach, the "better" parent might be adjudged to be the one with the "better" genes.

Genetic testing also could have an explosive impact on personal injury cases.

Under current law, a successful plaintiff in a medical malpractice or other personal injury case generally is awarded damages for future losses on the basis of life expectancy statistics. But savvy defendants may begin to require genetic testing on plaintiffs to find evidence that they have a predisposition to an early death, justifying a reduction in damages.

Forcing parties in custody or personal injury cases to undergo genetic testing could have a strong deterrent effect on parties who fear the consequences of learning unwanted facts about their genetic makeup.

In the South Carolina custody case, the wife was adamantly opposed to being tested for Huntington's disease, even though she faced the loss of her child if she refused. Facing a painful Sophie's choice, she simply disappeared.

The most significant direct legal impact of genetics may be in criminal law, an area in which DNA evidence already is commonplace. But the next step could challenge the very underpinning of the criminal justice system.

Criminal law is based on the idea of free will—that individuals "choose" to engage in criminal acts for which they must be punished.

But as geneticists increasingly claim to find genetic markers for antisocial behavior, the legal system

AP PHOTO

will be forced to reconsider the concepts of criminal intent and guilt.

A Dutch research group says it has found a gene linked to a propensity to aggression. How should the courts rule on a defendant's claim that he murdered because it was in his genes?

Judges already show some willingness to accept genetic defenses. In similar California cases, two admitted alcoholic lawyers embezzled money from their clients, but the one who claimed his alcoholism was genetic got a lighter sentence. In a murder case, the defendant was found not guilty after her violence was linked to having Huntington's disease.

Are All Genes Created Equal?

The great, vague specter of genetics is how it may eventually influence society's view of equality.

Much of the future research in genetics will not be related to disease but will focus on human individual and group traits, such as intelligence, behavior and race. Researchers now claim that they can distinguish between blacks and whites on the basis of differences in just three of the 100,000 genes in each human.

Arthur Caplan of the University of Pennsylvania Center for Bioethics has written, "Will the information generated by the genome project be used to draw new, more 'precise' boundaries concerning membership in existing groups? Will individuals who have tried to break their ties with ethnic or racial groups be forced to confront their biological ancestry and lineage in ways that clash with their own self-perception and the lives they have built with others?"

The potential exists for genetics research to produce findings that could undermine our conceptions of equality of opportunity, and individual and social responsibility.

Already, some physicians and lawyers suggest that people should have a duty to learn their own genetic status and to avoid having children who may be adversely affected by their genetic heritage.

In articles in both medical and Texas legal literature, Margery Shaw, a lawyer and geneticist, recommends that states adopt policies to prevent the birth of children with genetic diseases. She suggests that the prevention of genetic disease is so important that a couple deciding to give birth to a child with a serious genetic disorder should be criminally guilty of child abuse.

Shaw also suggests the imposition of tort liability for not sharing genetic information with relatives or for not undergoing genetic testing.

In the case of *Curlender v. Bio-Science Laboratories,* 106 Cal. App. 3d 811 (1980), a California appellate court stated in dicta that a child with a genetic defect could bring suit against her parents for not undergoing prenatal screening and aborting her.

In 1991, Bree Walker Lampley, a television anchor in Los Angeles, found herself caught up in the intense emotions that these issues can breed. When Lampley, who has ectrodactyly, a mild genetic condition that caused the bones in her fingers and toes to fuse, made public her decision to give birth to a child with the same condition, a radio talk show host and her listeners attacked the decision as irresponsible and immoral.

Lampley, along with several disability rights groups, filed a Federal Communications Commission complaint against the radio station for violating its personal attack rule and failing to present both sides of the issue. The complaint was denied.

Throughout the United States, people seem to have drifted into a mindset that assumes that if genetic information exists, it should be acted on and taken into consideration in a variety of social realms.

In *The DNA Mystique,* Nelkin and co-author Susan Lindee observe how quickly the new genetics has become part of popular culture. Their studies found that genes have been used to explain a wide range of social phenomena, including crime, job success, sexual orientation and adultery.

Nelkin and Lindee speculate on why such explanations are readily accepted by the public: "They can relieve personal guilt by implying compulsion, an inborn inability to resist specific behavior" and they can relieve societal guilt and give society an excuse to cut out social services by deflecting attention away from social and economic influences on behavior.

How genetic research will impact society remains to be seen.

Clearly, the promise of genetics is everywhere, and much fanfare accompanies each genetic discovery.

But less attention is focused on how we will use knowledge gained through genetic testing. When an article in the *Journal of the American Medical Association* heralded the discovery (later disputed) of a genetic marker for alcoholism, 140 newspapers and magazines ran articles praising the advance. Not a single article addressed the issue of what we would actually do if we identified individuals with a genetic propensity toward alcoholism.

The vexing question of how the fruits of genetic research should be used by society is on the table. Scientists are charting the map of the human genome, but the legal system will play a crucial role in determining where that map leads. ■

ABAJ/ROBERT DAVIS