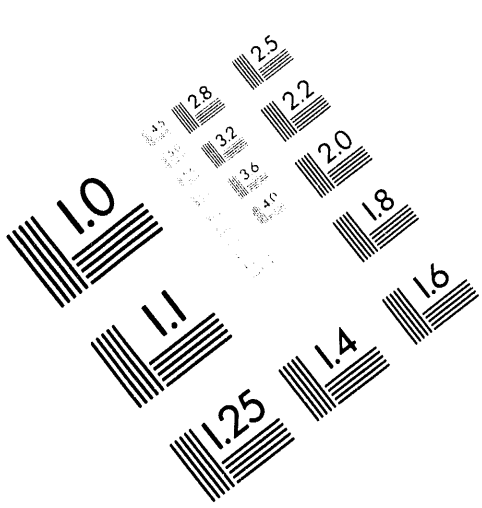

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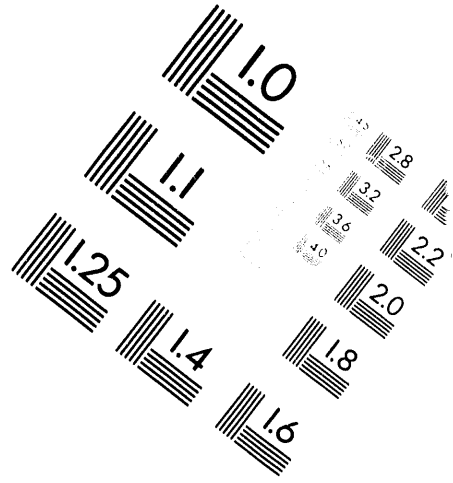

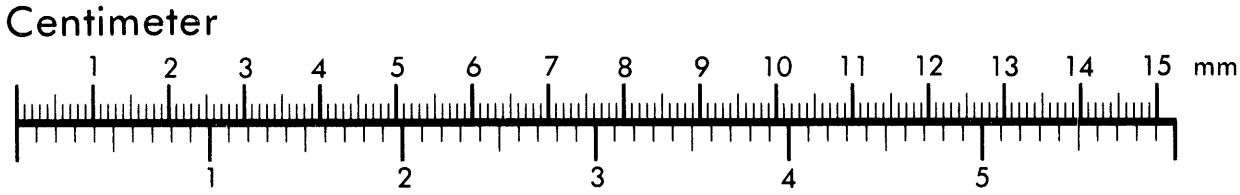

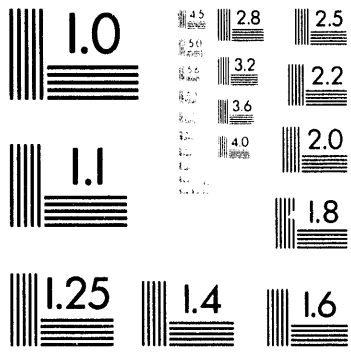

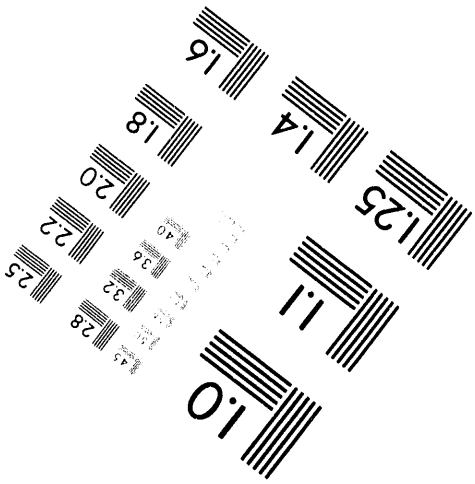

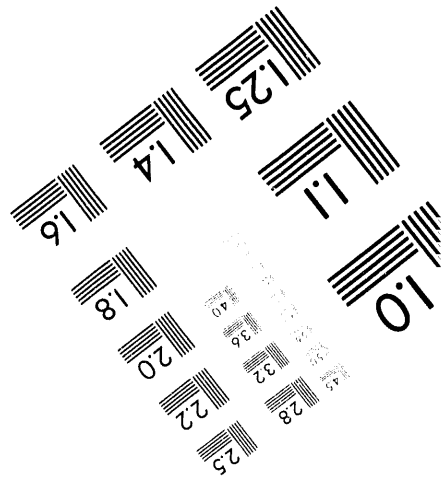

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MEDICAL INFORMATION AND THE RIGHT TO PRIVACY

SELECTED ABSTRACTS

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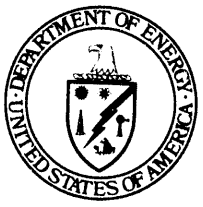

JUNE 1, 1994

U.S. DEPARTMENT OF ENERGY

OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
OFFICE OF OCCUPATIONAL MEDICINE

WASHINGTON, D.C. 20585

DISCLAIMER

FOREWORD

This report is a compilation of submitted abstracts of papers presented at the Department of Energy-supported workshop on medical information and the right to privacy held at the National Academy of Sciences in Washington, D.C., on June 9 and 10, 1994.

The aim of this meeting is to provide a forum to discuss the legal, ethical and practical issues related to the computerization and use of medical data, as well as the potential impact the use of these data may have on an individual's privacy.

Topical areas include an overview of the Federal and legal requirements to collect medical data, historical experiences with worker screening programs, currently available medical surveillance technologies (both biomedical and computer technologies) and their limitations. In addition, an-depth assessment of the needs and interests of a wide spectrum of parties as they relate to the use of medical data from both a legal and privacy perspective is provided. The needs of the individual, the public (e.g., blood and tissue banks), private enterprises (e.g., industry and insurance carriers), and the government (e.g., FBI) are discussed. Finally, the practical and legal issues relating to the use of computers to carry, store and transmit this information are also examined.

The abstracts are presented in the intended order of presentation as indicated in the agenda for the meeting.

TABLE OF CONTENTS

Page 1	.....	THE EXPERIENCE OF NIOSH
Page 3	.....	THE ADA AND JOHNSON CONTROLS
Page 5	.....	HISTORICAL AND PHILOSOPHICAL PERSPECTIVES
Page 7	.....	BIOMARKERS OVERVIEW
Page 9	.....	RECENT ADVANCES IN BIOMARKER TECHNOLOGY
Page 11	.....	MUTATIONAL SPECTROMETRY
Page 13	.....	CONFIDENTIALITY OF MEDICAL RECORDS
Page 15	.....	THE PHYSICIAN'S DILEMMA
Page 17	.....	USE OF PERSONALLY-IDENTIFIABLE INFORMATION IN RESEARCH
Page 19	.....	THE DOD DNA REGISTRY
Page 21	.....	CODIS, THE NATIONAL DNA IDENTIFICATION INDEX
Page 23	.....	BLOOD DONOR PRIVACY AND CONFIDENTIALITY
Page 25	.....	COMMERCIAL PERSPECTIVES
Page 27	.....	MONSANTO'S EMPLOYEE HEALTH DATABASE
Page 29	.....	COMPUTER TECHNOLOGIES

Page 31 .... LIST OF SPEAKERS

THE EXPERIENCE OF THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH WITH REGARD TO MEDICAL INFORMATION AND PRIVACY

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The National Institute for Occupational Safety and Health (NIOSH) is mandated by the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977 to conduct health hazard investigations and research in workplaces and mines. These responsibilities require the collection and use of medical and other records containing personal identifiers. This presentation describes the experience of NIOSH as it has functioned under relevant Federal laws and procedures.

NIOSH has authority to enter places of employment and to conduct various activities, including the copying of medical and other records, the administration of questionnaires, and conducting medical examinations and tests, according to procedures described in the Code of Federal Regulations (42 CFR Part 85 and Part 85a).

NIOSH research involving human subjects is carried out in accordance with the Department of Health and Human Services' regulations on the Protection of Human Subjects found in 45 CFR Part 46. Confidential records are maintained in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the implementing regulation of the Department of Health and Human Services (45 CFR Part 5b). The Privacy Act also requires that the agency publish in the Federal Register under Notices of Systems of Records for the Department of Health and Human Services a description of each system of records, including the planned use of the information. Whenever NIOSH collects confidential information, the data collection instrument lists these "routine uses" to inform the respondent of the only uses that can be made of the data he or she is being asked to provide.

Specific findings of individual employee medical examinations and tests are released by NIOSH only to the individual. The results are sent to a personal physician or other person only with the written authorization of the employee. Reports and publications of health hazard investigations and research studies contain only grouped data, without personal identifiers.

NIOSH also obtains medical information from death and birth certificates maintained by state vital statistics offices. NIOSH is able to offer a pledge of confidentiality tot he states based on the authority of section 308(d) of the Public Health Service Act. This section prohibits NIOSH from releasing information except for the purposes for which the information was provided, unless those persons or

establishments have consented to its release.

The Freedom of Information Act (FOIA), found in 5 U.S.C. 552 (with implementing regulations found in 45 CFR Part 5), also governs the release of information that NIOSH obtains in the course of its research.

THE ADA AND JOHNSON CONTROLS

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Privacy involves a condition of limited access to an individual. It is the right of individuals to be left alone, to have some element of their person or personal life free from intrusion by others. It includes the right of an individual to keep certain medical information free from disclosure to other parties. Confidentiality involves an individual's interest in sensitive information. It refers to the right of an individual to prevent the redisclosure of certain information that was developed within a confidential relationship. Both the Americans with Disabilities Act (ADA) and the Supreme Court's decision in International Union, United Auto Workers v. Johnson Controls, Inc., 499 U.S. 187 (1991) (Johnson Controls) deal with important issues relating to the privacy and confidentiality of medical information.

Title I of the ADA attempts to prevent discrimination in employment against individuals with disabilities by preventing employers from gaining access to irrelevant ("non job-related") medical information at critical times in the employment relationship. It also attempts to enhance the dignity and prevent the stigmatization of individuals with disabilities by limiting the scope of medical inquiries of applicants and employees and ensuring that all medical information within the possession of employers is kept confidential to the fullest extent possible. Thus the ADA attempts to protect both privacy and confidentiality.

The Supreme Court's decision in Johnson Controls held that an employer's policy of excluding all fertile female employees from jobs where there was exposure to inorganic lead due to fears of the women becoming pregnant and having a child with lead-mediated birth defects constituted sex discrimination in violation of Title VII of the Civil Rights Act of 1964. At first glance, it might seem that this "fetal protection-sex discrimination" case is unrelated to the issues of medical privacy and confidentiality. On further reflection, however, it is very closely related. The Court held that, so long as it does not affect the ability to perform the essential elements of the job, an employee's reproductive status is not relevant to the employer's decision to hire, fire, or assign an individual. Thus, Johnson Controls is very much a privacy case. It is also an autonomy case, in which the Court held that the decision whether to accept certain reproductive risks belongs to the individual employee and not the employer. In general terms, this view is consistent with the ADA, although the ADA does permit a narrow exception where employment of an individual would create a "direct threat" to the health and safety of others or the individual.

HISTORICAL AND PHILOSOPHICAL PERSPECTIVES

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This paper is the last of three parts presented at the Department of Energy meetings on biomarkers, medical records, and genetic testing held in 1993 at the National Academy of Sciences; in May 1994 in Santa Fe, New Mexico; and June 9, 1994, at the National Academy of Sciences. It is an historical and philosophical synthesis of social, economic, cultural and ethical issues that workers and everyone else face.

Identifying established precedents to the perceived consequence of unfettered genetic testing of beryllium-exposed and other workers, the paper explores the recurrence and reinforcement of despair in caste systems that results in suicide (the traditional measure of anomie or social disease) and parasuicide. Empirical data are drawn from an on-going field study of uranium miners and other workers in the nuclear weapons industry using human ecological methods. The genetically-defined caste evolving at this time is evaluated by the values of norms of the open system society, idealized and increasingly being achieved by Humankind.

Short and long term interventions possible through the courts, national and international legislatures, and administrative and professional structures are suggested.

BIOMARKERS OVERVIEW

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Occupational diseases are now being assessed at the cellular and molecular levels; this presents new opportunities for prevention and control. The key to these opportunities is the ability to detect biological markers that reflect exposure, response, and susceptibility. Biological markers are now new, however. Biological markers such as blood lead, urinary phenol levels in benzene exposure, and liver function assays have long been used in occupational and public health research and practice. What distinguishes the current generation of markers from preview markers is a greater degree of analytical sensitivity and the ability to describe events that occur earlier in the progression between exposure and clinical disease. There are now new domains of response that were not known to exist 20 years ago. Accompanying this sensitivity is the increased requirement to consider the numerous factors that can influence the appearance of biological markers. It has been observed that all workers with similar exposure do not develop disease or markers indicative of exposure or disease. Various acquired and hereditary host factors are responsible for this variation in responses. The role of assessing the nature and degree of variation between individuals is of paramount importance. Finally, the use of biological markers in occupational health research and practice also bring new ethical and legal considerations into high profile. This paper presents my personal opinions on how biological markers can contribute to occupational health efforts and the new requirements that they bring to the field. As with any technological change, the more we can anticipate the impact, the better our ability to adjust.

RECENT ADVANCES IN BIOMARKER TECHNOLOGY

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As knowledge of the basic biochemical steps involved in various disease processes has grown in recent years, so has the potential for using biochemical indicators of those steps as molecular biomarkers for the study of disease evolution in human populations. In addition to allowing the study of molecular mechanisms of disease in vivo, it has been presumed that these biomarkers will contribute to the prevention of disease. This presumption is based on the belief that certain biomarkers will be better able than current approaches to identity those individuals at-risk for the development of disease prior to the time of clinical diagnosis, i.e., that they will have predictive value.

Some recent studies of biomarkers of exposure and response suggest that this may be possible to a certain degree. Take hepatocellular carcinogenesis as an example. Ingestion of food stuffs contaminated with aflatoxin (AFB) and chronic infection with hepatitis B virus (HBV) are considered risk factors for hepatocellular carcinoma (HCC). However, the likelihood that a given individual with a history of potential exposure to AFB or HBV will develop HCC is still relatively small. Biomarkers of carcinogenic exposure and response may be able to better predict those individuals in exposed populations who will actually develop HCC. Thus, in a recent study in Shanghai, 18, 244 mostly middle-aged males were recruited between 1986 and 1989 and followed up for HCC occurrence to 1992. At the time of recruitment, a blood and a urine sample were obtained and subsequently analyzed for serum HBV surface antigen positivity and urinary AFB metabolites in 50 resultant cases of HCC and 267 matched controls. Although no significant association was found between estimated dietary AFB consumption and HCC risk, a highly significant association was found between the biomarkers of exposure (HBV surface antigen and urinary AFB metabolites) and HCC risk (1). Furthermore, it is believed that activation of cellular oncogenes and inactivation of tumor suppressor genes may play a role in the subsequent biological response to environmental carcinogens in HCC development. Thus, the oncogene c-erbB-2 is frequently over-expressed in HCC and can be detected in serum by quantitation of its extra-cellular domain (ECD). In another recent study in Taiwan, 9,691 middle-aged males were recruited between 1984 and 1986 and followed up for HCC occurrence to 1990. At the time of recruitment, a blood sample was taken and subsequently analyzed for c-erbB-2 ECD in the 23 resultant cases of HCC and 23 matched controls. Elevation of serum c-erbB-2 ECD was found to be significantly associated with HCC risk, and those individuals with elevated serum c-erbB-2 ECD had times between serum collection

and clinical diagnosis from 2 to 60.5 months (2). In addition, it has been suggested that AFB may be responsible for the specific pattern of mutations in the tumor suppressor gene p53 in HCCs from AFB-endemic areas. Many p53 mutations result in increased stability of the p53 protein with excess accumulation in cells, and preliminary evidence suggests that increased serum p53 may be detectable during the development of HCC prior to the occurrence of clinically detectable disease. Similar studies in different cancers and other diseases have begun to yield similarly suggestive results of the potential predictive value of such biomarkers. Ultimately, combinations of various biomarkers of susceptibility, exposure and response may be brought to bear to help predict disease outcome. The useful applicability of such predictive biomarkers will depend on a balance of the certainty of the outcome against the risks of the intervention to prevent the outcome; for example biomarkers of exposure, being farther removed from the clinical outcome may be of lower predictive value (due to the necessary occurrence of further steps in the causal pathway), and thus warrant less risky interventions than biomarkers of response that, being closer to the clinical end-point may have higher predictive value, and thus warrant more risky interventions.

However, the potential ability of biomarkers to better identify individuals who will develop disease in the future raises serious ethical concerns. Inappropriate access to such information could adversely affect an individual's employability and insurability. Further, the affected individual's appropriate access to such information may only result in added years of psychological distress unless effective and appropriate interventions that can prevent the development of disease are also available.

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MUTATIONAL SPECTROMETRY: POPULATION POLYMORPHISMS AND SOMATIC MUTATIONS

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The technology of recognizing and identifying mutant DNA sequences permits any gene in any human to be examined using small blood samples or exfoliated epithelial cells from skin, colon or bladder. However, in screening for rare variants in the human population or in determining the pattern of somatic mutations in human tissues new technology has been required.

We have found that the combination of capillary gel electrophoresis, differential DNA melting equilibria and high fidelity PCR permits us to measure mutations in DNA sequences of 100 bp at frequencies at or below 10^{-6}. It is thus possible to plan population screening efforts in which, for instance, 10^4 blood samples are combined to search for rare polymorphic mutations. The technology may conceivably be used to detect early signs of certain kinds of tumors. But our fixed purpose is to examine mutational spectra in humans to discover if they will point to the primary causes of human mutations by endogenous mechanisms or external agents.

The social cost of uncertainty as to the role of environmental agents in human disease is high. We hope to bring evidence to our courts that will permit confident adjudication of toxic tort cases and, with experience, help provide a scientific basis for environmental regulation and community practice.

CONFIDENTIALITY OF MEDICAL RECORDS

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As Representative Stark has said, "There is no consistent, comprehensive protection for privacy in health care information." Whenever one starts to explore what is or is not confidential, one realizes that there is a morass of conflicting custom and law at all levels from local to federal. Even the traditional doctor/patient relationship which is often recognized in common law, does not always apply to medical records generated at the place of employment.

This talk will discuss my experience in addressing the issue of confidentiality of employee's medical records. It will be based on personal experience and conversations with colleagues.

My conclusion is that we need comprehensive federal legislation which will define confidentiality of medical records no matter where or how they are generated, and specify when and under what circumstances information may be released without the patient's knowledge or consent. Since many employees may have medical records on file in more than one country, there is need for similar legislation in all countries.

THE PHYSICIAN'S DILEMMA

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The ethical imperative that drives the privacy and confidentiality of medical information dates to antiquity. Immediate and wide access to computerized medical information, coupled with calls for national health care reform, are contemporary challenges to the integrity of medical information that face all medical practitioners. Occupational medicine physicians, in particular, practice in a unique setting that poses threats to confidentiality in formulating medical decisions that involve a person's ability to work. These decisions necessitate the transmittal of certain types of medical information. Pre-placement evaluations, treatments of work-related injuries, consultations related to the work-relatedness of an illness, drug testing, medical surveillance examinations and assessment of needlestick injuries are common examples where confidentiality of medical information must be addressed. The framework for the evaluation of most of these requests for medical information is based on federal and state legislation and regulation, including the Americans with Disabilities Act, workers compensation statutes and standards of the Occupational Safety and Health Administration, including access to employee exposure records, hazard communication and bloodborne pathogens. Ethical codes also play a major role in providing a framework for decisions, including those of the American Medical Association, the American College of Occupational and Environmental Medicine, and the International Commission on Occupational Health, all of which address medical confidentiality. Despite these guides, misunderstanding of medical confidentiality is common among both medical practitioners and business personnel. Moreover, ethical restraints faced by practitioners in releasing information do not hold for many third parties, such as health insurers. Full disclosure to patients regarding any request for their medical information, even under subpoena, is recommended, along with the preparation of a signed release. This paper will discuss common examples in occupational medical practice where confidentiality concerns are addressed.

CONSIDERATIONS IN USE OF PERSONALLY-IDENTIFIABLE INFORMATION IN RESEARCH

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There are ethical principles, government policies, and legal controls governing use of individually-identifiable personal information for research. In many instances, it is impractical or impossible to find individuals to obtain their consent for use of their records. Use of information for research without individual consent under these circumstances has been found to be acceptable if rigorous steps are taken to ensure that the individuals are not harmed in any way by use of their records.

Those intending to use personally-identifiable information for research need to be aware of the body of policy and ethical thinking regarding use and disclosure of personal information, of the applicable laws (both Federal and State), and of the Federal rules for protection of human research subjects. A basic principle is that of functional separation: information obtained for research and statistical purposes should never be used to make decisions affecting the rights, benefits, or privileges of an individual.

Federal records (including, in general, contractors' records) are subject to the Privacy Act of 1974. The Act imposes requirements on Federal agencies which create or operate data systems, including announcement in the Federal Register of the existence of records, and rights of access and correction by the subject. There are some substantive rules on what disclosures are allowed, but agencies are given great latitude in identifying what additional disclosures they wish to make (called "routine uses").

Many government agencies have identified disclosures for research purposes as routine uses. Some agencies are governed by specific statutes governing their use and disclosure of personal information, with more restrictive rules than the Privacy Act.

Federal agencies have regulations, applicable to research conducted or supported by them, to protect the interests of research subjects. They include requirements for review by institutional review boards, and certain substantive requirements regarding such matters as informed consent and the circumstances under which consent may be waived.

Policy thinking about use of personal information is found in the work of government commissions, in private studies, and in academic work. The work of the

Privacy Protection Study Commission (1977) is still a valuable guide to policy choices about the use of personal information. The Commission understood and supported use of administrative records in research, under careful conditions to protect the interests of the research subjects.

More recently, the Committee on National Statistics' Panel on Confidentiality and Data Access made valuable recommendations on the use of administrative records for research and statistical purposes (1993). Current efforts to develop health record privacy legislation, and the policy thinking surrounding the national and global information infrastructure, are again focussing policy makers and the public on rules for use of information about individuals.

THE DEPARTMENT OF DEFENSE DNA REGISTRY

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Identification of human remains is a priority for the U.S. military. While fingerprint and dental identification remain the predominant means of identification, DNA typing has been added to the arsenal of identification techniques used. DNA typing was first performed to assist in identifying the war dead during Operation Desert Storm in 1990. The utility of this technique has since been demonstrated on numerous occasions. In June of 1992, the military began collections of DNA from service members for storage as primary reference samples in support future DNA identification efforts if and when needed. Three samples are collected: 1) a bloodstain card for storage in the health record, 2) a bloodstain card for storage in the central repository, and 3) an oral swab for storage in the central repository. These samples are physically secure. The computer system which is used for specimen tracking purposes is secure. Identification information is considered confidential. The Assistant Secretary of Defense for Health Affairs has authorized the use of the DNA specimens for identification purposes only. The Department of Defense DNA Registry, organizationally composed of the Armed Forces DNA Identification Laboratory and the Department of Defense DNA Specimen Repository, has received great praise in its efforts towards the humanitarian goal of returning remains to their loved ones.

CODIS, THE NATIONAL DNA IDENTIFICATION INDEX

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In 1990, the FBI began development of a national DNA identification index, CODIS. The concept driving this development is the rarity of a DNA profile obtained from the successful analysis of body fluid stains left at crime scenes. Given the recidivistic nature of persons committing rape and other violent crimes, and the fact that body fluids of the perpetrator are often left at crime scenes, a national computer-based system of storing and comparing DNA records can result in the successful application of DNA profiling in the fight to prosecute and deter violent criminal behavior.

The FBI has undertaken the development of a fully integrated local/state/national law enforcement system of DNA records. This system, called CODIS, will establish four files of DNA records: the population file, the forensic index, the convicted offender index, and the missing persons index. These files will exist at local, state, and national levels. These files will be used in the generation of investigative leads by identifying associations among DNA records in the indexes to the DNA record obtained during an investigation of a violent crime or missing person case. The population file will assist in the statistical interpretation of DNA profiles from case work.

Twenty-five states have enacted legislation that requires individuals convicted of certain crimes, generally including homicide and/or sexual assaults, to provide a sample of their blood for DNA profiling (convicted offender statutes). The DNA records of these individuals are then stored for reference use by law enforcement laboratories. Federal legislation is pending which would establish national standards to address data integrity and access control to CODIS.

BLOOD DONOR PRIVACY AND CONFIDENTIALITY

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Annually, the American Red Cross Blood Services (ARCBS) collects about 6 million units of blood from some 4 million donors, and serves more than 2 million recipients with blood and its components and derivatives. ARCBS always tries to recruit safe donors, to provide potential donors with risk information, to ask health history questions, to provide opportunities to self-exclude, to perform laboratory tests on samples, to inactivate any viruses (blood derivatives only), and to check all donations against a file of previously deferred donors. The health history and examination process also helps assure that donation will be safe for the donor. It is the donor's right to have the health history conducted with privacy and to have the history and test information managed in confidence. Further, (1) ARCBS must meet FDA requirements for privacy and (2) must achieve conditions which enhance the likelihood that the donor will produce an accurate health history and return for future donations.

At the blood collection site, a new system is being implemented which will first check the donor against the confidential list of deferrals. Then donors are given the information sheet, "What You Must Know Before Giving Blood." It indicates that questions will be asked in a private and confidential manner about past and present health and lifestyle. It states that there will be a private opportunity to indicate if the donated blood is safe and also that there will be an opportunity to call back later with second thoughts. It notifies donors that ARCBS maintains a confidential list of people who may be at risk for spreading infectious diseases. Lastly, it cautions that, when required, donor information, including test results, are reported to health departments, military medical commands, and regulatory agencies. The required donor consent recognizes that, if the history or test information requires, the donor's name will be entered on a list of deferred donors.

A standard set of criteria are applied to health history and test information to determine if the donor and his identifiers must be entered into the confidential list, the Donor Deferral Registry (DDR). ARCBS now maintains system-wide, and with 45 local components, the DDR; deferred donors are categorized for indefinite or time-limited deferrals. The system-wide DDR now contains approximately 300,000 records and is updated monthly with regional inputs. All donors are screened against both system-wide and regional entries before their blood is deemed suitable for use. Donors who are entered in the file receive notification and counseling about the significance of their test results. A donor must sign a written release before ARCBS provides any information to a physician. The confidentiality of the system is supported

by staff training, signed confidentiality statements, restricted physical access to records, restricted access to computers and computer files and by communicating with donors in ways appropriate to the specific content of the message.

American Red Cross Tissue Services (ARCTS) also require that all communication and records pertaining to donors, donor families and recipients must be treated as confidential. Prior to tissue processing , the ARCBS DDR is checked for all donors. Living tissue donors who meet deferral criteria are entered into the DDR.

To date, there have been no donor challenges to the confidentiality of the DDR. The complex systems designed to protect the safety of the blood supply can be managed confidentially to protect the rights of the donors.

COMPUTERIZED PERSONAL AND MEDICAL INFORMATION SYSTEMS: COMMERCIAL PERSPECTIVES

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Health insurers (specifically, companies that provide medical expense coverage) and managed care organizations have a variety of needs for personal medical information. These include: claims adjudication, fraud detection and prevention, utilization review, case management (including rehabilitation), and various quality and outcomes measurements, including appropriateness of care and treatment protocols. In addition, pending enactment of comprehensive health care/health insurance reform, personal medical information is necessary to evaluate the insurability of that small segment of the population that purchases health insurance on an individual basis.

On a larger scale, aggregated medical information (with personal data deleted or limited) is needed in order to determine broad measurements of health care quality, outcomes and standards of care. Aggregated data are also necessary for determination of health care costs and development of analytical tools for assessment of health care utilization, provider effectiveness, and future policy direction.

MANAGEMENT OF DATA SECURITY IN MONSANTO'S EMPLOYEE HEALTH DATABASE

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Monsanto's employee health database, MARS, contains several million data records. Most of the data obtained in the course of routine medical assessments of employees are captured by this system. This includes physicians' diagnoses, interpretations, and physical findings. From the inception of MARS and its predecessor, MEHI, securing these data has been a major focus of Monsanto and those responsible for the system. Access to medical data on individual employees is limited to the medical professionals with responsibility for the health of those employees plus the minimum number of support personnel in data entry and programming for operation and maintenance of MARS.

The MARS data sets are managed by an IBM software product, SQL/VM. This is an SQL-compliant, relational database manager. Most, if not all, relational database managers such as DB2, Oracle, and RDB allow for the creation of "views" of tables. Utilizing views of tables, access can be limited by table, location(s) within a table, individual columns within a table, and any combination of these parameters. Additionally, read, write, modify, and delete authority can be granted down to the level of a single field in any table or view.

Although relational database managers provide considerable flexibility in the development of security systems, it is essential that security be one of the primary considerations in planning any new applications or new systems. The expected users of the data must assume responsibility for planning the security system equal to that expected of the programmers and system support staff. While specific functions may be delegated, the security of the data must remain the ultimate responsibility of the lead user or system coordinator.

COMPUTER TECHNOLOGIES

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In the advertising rhetoric of one of the major workstation vendors in the United States, "the network is the computer." This phrase not only represents that vendor's approach to hardware and software design, but symbolizes a major revolution in computing practice. While many of our established notions about large scale computing are based on the large "mainframes" common only a few years ago (and still common in some institutions), modern computing environments are built around distributed systems and "client-server" data access. Almost all of the currently competitive database management systems are built around the client server model, where data files may reside on several machines in "mini-databases" maintained by the generators or primary curators of the information, and users access the data via intelligent client routines running on local microcomputers or workstations. This model, which had its early foothold in academic settings, has begun its broad sweep through the commercial world and is making steady progress in the hospital and broader medical environment. In today's competitive world of health care, information is a valuable component of the health care equation and powerful distributed systems are finding their way into the major managed care provider networks. One goal of the revolution in computing is the provision of an "integrated" computing environment. Integration in this context means that the user has one "workstation" which provides access to database servers, electronic mail, word processing, spreadsheets and presentation software. Data moves freely between these various applications on this one machine, either by cutting and pasting, or by direct interprocess communication. This vision is based on a system of "open architecture," a term which refers to the heterogeneous multi-vendor environment which has become increasingly common. The basis for this"openness" is a group of de facto conventions and standards which go beyond the proprietary offerings of any single vendor and provide the vehicle for effective communication between heterogeneous systems. These "standards" have been applied to specific software, network communications, and many other areas.

Riding the wave of client-server computing, over the past four years there have been dramatic changes in how information of all kinds is provided across the Internet which have transformed it into a system where the average computer user can sit at his/her desk-top PC/Mac and literally point and click around the world. Perhaps not coincidentally, the Internet is in an explosive growth phase, with a new network being connected to the Internet every ten minutes. Many of the changes have been driven by the development of three network protocols, WAIS, Gopher, and World Wide Web (WWW), and several software applications which implement these protocols and have dramatically changed the face of the Internet. All three protocols are client-server network-based information dissemination systems, and a variety of client and server

applications are available in the public domain. Biologists are at the forefront of this wave of change and are helping shape the direction of new services. Of central importance to molecular biology and biochemistry is access to databases which contain information about molecular sequences and their function, 3D structures of proteins, genetic mapping information, and the associated literature citations.

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