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The Genetic Privacy Act: A Proposal for National Legislation

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ARTICLES

THE GENETIC PRIVACY ACT: A PROPOSAL FOR NATIONAL LEGISLATION

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ABSTRACT: This article describes the development and the major features of the proposed Genetic Privacy Act.

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Privacy is a major issue in medical law, and genetics is a major force in contemporary medical science. Nonetheless, the combination of these two fields has only recently been seen as central to both individual rights and medical progress. Disclosures in June of 1996 that White House officials had wrongly acquired and read FBI files of raw background checks of prominent Republicans reminded Americans that there is no such thing as a completely secure and secret file of personal information. Had these files contained DNA profiles or samples, they would have supplied additional information about the unsuspecting individuals—information that could be used against the individuals without their knowledge. In late June 1996, Senator Pete V.

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Domenici (R-N.M.) introduced S.1898, the Genetic Confidentiality and Nondiscrimination Act of 1996 (GCNA), which was based in large part on the proposed "Genetic Privacy Act of 1995" (GPA) drafted by the authors.[1] This article outlines the purpose and provisions of the GPA. Along the way, it highlights some of the differences between the GPA and the GCNA.

I. THE HUMAN GENOME PROJECT

The Human Genome Project (HGP) is an international effort to create a high resolution picture of the human genome and to sort genes from the vast regions of DNA that appear to have no function. Molecular geneticists theorize that decoding the information in this human blueprint will advance our understanding of every function of the human organism that is even partially affected by genetic inheritance. The genes responsible for several diseases including Huntington disease and cystic fibrosis have already been located. Decoding of other sections of the genome has identified changes in genetic material that seem to increase susceptibilities to other diseases, such as some forms of cancer and heart disease. While these diseases are likely to result from both genetic and environmental factors, the ability to read sections of the genome contributes to knowledge of the risks that an asymptomatic individual has of developing disease in the future. If the speculation of some geneticists proves correct, the human genome may also tell us about the development of a wide range of behavioral characteristics such as alcoholism, aggressiveness, risk taking—and even happiness.[2]

The tasks of decoding the entire genome and sorting scientific genetic facts from science fiction will probably take another decade, but that has not inhibited the desire to read the bits of the genome decoded to date. Testing kits for a mutation of a normal gene called BRCA1, which is associated with increased risk for breast cancer, are already being marketed despite concerns about the misunderstanding and misuse of information derived from test results. What the presence of discernible mutations in such genes means in terms of disease prediction is not known for certain. Nonetheless, the analysis of a person's DNA will have a significant impact on how individuals view themselves and are viewed by others. This raises serious issues of control of

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1. GEORGE J. ANNAS, LEONARD H. GLANTZ, & PATRICIA A.ROCHE, THE GENETIC PRIVACY ACT AND COMMENTARY (1995) (available by request from the Health Law Department, Boston University School of Public Health, 80 East Concord St., Boston, MA 02118, and also at http://www.busph.bu.edu/Depts/ HealthLaw/). This report was funded by the Ethical, Legal & Social Implications of the Human Genome Project, Office of Energy Research, U.S. Department of Energy, and the Boston University School of Public Health. *See generally* George J. Annas, Leonard H. Glantz, & Patricia A. Roche, *Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations*, 23 J. L., MED. & ETHICS 360-66 (1995).

2. Daniel Goleman, *Forget Money: Nothing Can Buy Happiness, Some Researchers Say*, N.Y. TIMES, July 16, 1996, at C1.

genetic analysis and genetic information. Who should decide what genetic tests, if any, should be performed? Who should have control of DNA samples that contain the individual's entire genetic blueprint? Should all genetic information be treated the same way? How should access to private genetic information be controlled?

Task forces and committees convened by the Ethical, Legal and Social Issues Working Group of the HGP (ELSI), various professional associations, and state legislatures have focused on the legal and ethical issues presented by the HGP. Throughout their discussions, it has been recognized that present laws will not adequately protect the information that will be created in this new genetic era. Exactly what form or scope new laws should take, however, continues to be debated.

The initial question is whether genetic information is so unique that it should be treated differently from other medical information. If genetic information were not significantly different from other highly personal information, particularly medical information, we could simply amend current laws governing the confidentiality of other sensitive information to include genetic information. The primary feature of DNA that argues for legislating additional safeguards is that the information contained in a DNA sample can be used to estimate the likelihood that an asymptomatic individual will suffer from a variety of conditions in the distant future. In this way, the individual's genome can be thought of as a coded probabilistic future diary.[3] Prediction may be possible only through decoding the individual's DNA, but once created, this information can profoundly affect the individual's self-perception and life choices. Educational pursuits, career decisions, even retirement planning can be based in part on genetic factors. Reproductive choices may be based not only on the individual's risk of a major illness, but the probability that a particular genetic disease or disease susceptibility will be passed on to offspring. Decoding DNA also divulges information about a person's parents, siblings, and children and can therefore affect how family members perceive and relate to one another as well.

The greatest risk to individuals as the result of the creation and disclosure of genetic information, however, comes from the use that governments and others who control resources can make of such information. As history has shown, genetic information and misinformation has been the basis for vicious discrimination against those viewed as undesirable or unfit because of genetic status. Because all genomic information about an individual is contained in each DNA sample extracted from that individual, stored samples will provide more genetic information than was imagined when samples were originally

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3. GENE MAPPING: USING LAW AND ETHICS AS GUIDES 9 (George J. Annas & Sherman Elias eds., 1992); *see also* George J. Annas, *Privacy Rules for DNA Databanks: Protecting Coded Future Diaries*, 270 JAMA 2346 (1993).

taken (as our knowledge of the function of various genes increases). Threats to individual privacy and autonomy are therefore presented not only by the performance of currently available genetic tests, but by the longtime storage of samples that could be subject to additional analysis in the future. Thus, DNA storage issues must be considered separately from issues regarding the storage and release of information derived from DNA testing.

As a result of these concerns, in 1993, under contract with the Department of Energy portion of ELSI, we undertook the development of guidelines for DNA banking which would protect the privacy of individuals whose DNA was stored. As we worked on this issue, however, we concluded that DNA banking was a small part of the genetic privacy puzzle. We concluded that it was necessary to regulate the acquisition of DNA and its analysis, as well as the storage of collected DNA samples. Consequently, and with input from and final endorsement of the ELSI Working Group, we crafted a much broader legislative proposal, the GPA. Though written as a proposal for federal legislation, it can also serve as a model for state legislation, and as a source of rules and regulations that could be adopted by anyone engaged in the collection, storage, and analysis of identifiable DNA samples.

The overarching premise of the Act and its comprehensive set of rules is that no stranger should have or control identifiable DNA samples or private genetic information about an individual, unless that individual has specifically authorized the collection of DNA samples for the purpose of genetic analysis, has authorized the creation of that private information, and has access to and control over the dissemination of that information.

II. CORE PROVISIONS OF THE GPA

The core provisions of the Act are that:

- No collection of DNA for analysis is permissible without an informed and voluntary authorization by the individual or his or her legal representative.
- Those conducting DNA analysis are prohibited from doing so unless execution of written authorization by the individual or legal representative has been verified.
- No analysis may exceed the scope of the written authorization.
- DNA is the property of the individual from whom it is obtained.
- DNA samples must be routinely destroyed once the authorized analysis has been completed.
- Anyone who holds private genetic information in the ordinary course of business must keep such information confidential and is prohibited from disclosing it unless the disclosure has been authorized in writing by the individual or legal representative.

These rules govern all circumstances in which individually identifiable DNA samples are collected for analysis. Collection and analysis of DNA without prior authorization is permissible only for law enforcement identification activities when otherwise authorized by federal or state law[4] and for the identification of dead bodies, provided that the kind of analysis that is conducted is limited to DNA typing.[5] Such profiling analysis results in information useful for identification but which is otherwise without meaning. It is similar to fingerprinting in that it involves unique individual markings that reveal no informative details about the source of the fingerprint. It does not result in the kind of genetic information that needs protection, and the exception for this purpose does not conflict with the underlying premise of the GPA.

Prior authorization from the individual is also not required when DNA is collected pursuant to a court order, provided that the order is drafted according to the statutory specifications.[6] This exception could be invoked in paternity actions and other cases in which the genetic condition of a party is at issue. But even in these cases, genetic analysis is limited in such a way that it would rarely, if ever, result in what we consider private genetic information. In most such instances, identity is the issue.

The prohibitions and restrictions on collection and analysis of DNA apply to activities involving *identifiable* DNA samples.[7] Consequently, enactment of these rules would not affect use of non-identifiable DNA samples for research because there are no privacy issues involved when samples are not and cannot be linked to an individual. This is perhaps the major difference with the GCNA, which is based on the premise that all DNA is "identifiable" through DNA fingerprinting, and thus, individual consent must be obtained for all research.

III. AUTHORIZATION REQUIRED

To facilitate informed decisions regarding DNA analysis, the GPA prescribes several verbal disclosures that must be made before written authorization is obtained.[8] Requiring verbal disclosure provides persons to be tested with the opportunity to ask questions and to obtain additional information. These disclosures are designed to include information regarding the

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4. Genetic Privacy Act [GPA], *supra* note 1, § 122. Section 402 of the GCNA adds the U.S. military to this exception.

5. *Id.* § 121.

6. *Id.* § 123.

7. An identifiable sample is one that is linked to any individual identifier "such as name, address, Social Security number, health insurance identification number, or similar information by which the identity of a sample source can be determined with reasonable accuracy, either directly or by reference to other available information." *Id.* § 3(h), (i).

8. *Id.* § 101(b).

potential benefits and risks of proceeding with an analysis. Therefore, the individual must be informed about the information that can reasonably be expected to be derived from the analysis, and the utility, if any, that such information might have for that individual. Although the average person is familiar with having tests that measure a physical condition, such as blood cholesterol levels, it is unlikely that most people would anticipate the implications that undergoing a genetic analysis might have, not just for themselves, but for others as well. Therefore, the GPA requires that the person be informed that testing might reveal something that is also of importance to genetic relatives and consequently will have to decide whether or not to share that information with family members.[9] We view the duty to share needed information with family members as a purely moral obligation; nothing in the GPA legally obligates anyone to share genetic information with anyone else.

Because of the interest that insurers, employers, or others may have in the results of a DNA analysis, the person must also be warned of the possibility that others may condition future benefits on the disclosure of information resulting from such analysis or from the very fact that such an analysis was performed. The GCNA specifically restricts the *use* that employers and insurance companies can make of genetic information.[10] Use restrictions are beyond the scope of the GPA, but they can provide important protection as well. Use restrictions, however, are after-the-fact and difficult to enforce. They cannot be a substitute for privacy protection.

In addition to receiving verbal disclosures, before deciding whether to proceed with the collection and analysis of DNA, individuals must be provided with a notice of rights and assurances.[11] The final procedural requirement before collection and analysis of a sample can legally proceed is the execution of a written authorization. The information that must be included is described in detail in the Act.[12] For example, the purpose of the analysis and the identification of the entity that will perform it must be explicitly stated in the authorization. Without such informational requirements, the GPA's substantive rules could not achieve their purpose. Compliance with these requirements will create a "chain of custody" of identifiable samples so that individuals can effectively exercise the rights established by the substantive provisions. For example, the GPA provides that an identifiable DNA sample is the property of the individual who is its source and grants the individual the right to destroy the sample at any time.[13] These provisions would be of little use to individuals unless they were made aware not only of the existence of the legal rights and

9. *Id.* § 101(b)(8).
10. GCNA § § 301, 302.
11. GPA, *supra* note 1, § 105.
12. *Id.* § 103(a).
13. *Id.* § 104(a), (b).

obligations created by the GPA, but also of where their DNA samples are located. Therefore, a copy of the authorization must also be provided to the individual.[14] In addition, any storage facility that intends to transfer its operations to someone who will use the sample for a substantially different purpose than was originally authorized must notify the sample source and provide an opportunity to reclaim or order destruction of stored samples.[15]

IV. WHAT GENETIC INFORMATION IS PROTECTED BY THE GPA?

The definition of "private genetic information" in the GPA is based on our conclusion that there is a subset of genetic information that is unique and should be particularly guarded. This subset, termed "private genetic information," consists of:

> any information about an identifiable individual that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA marker or markers, and which has been obtained:
>
> (1) from an analysis of the individual's DNA; or
>
> (2) from an analysis of the DNA of a person to whom the individual is related.[16]

This definition excludes observations of obvious and manifested genetically determined characteristics such as height, eye color, and symptoms of some diseases. This publicly accessible genetic information cannot be considered private. In addition, this definition excludes information about genetic conditions that would be knowable from the development of family medical history or through biochemical analyses, such as blood tests for the presence of gene products. For example, an individual's status as an asymptomatic carrier of a gene associated with a particular disease may be inferred from knowing that certain relatives suffer from that disease. Similarly, the probability that a young woman has a genetic predisposition to breast cancer may be deduced from examining the occurrences of breast cancer in her family. Both of these pieces of information (carrier status and predisposition to disease) are highly private and from a theoretical standpoint should be governed by these rules. Because the GPA's narrow definition does not include genetic information derived from family history and tests for gene products, some genetic information that is private will not be protected. However to define more broadly private genetic information (as the GCNA does)[17] presents a vexing

14. *Id.* § 103(c).
15. *Id.* § 162.
16. *Id.* § 3(m).
17. GCNA § 3(11).

practical problem. How are we to distinguish between such genetic information and other medical information? Notations in medical records of the private genetic information subject to these rules will inevitably necessitate some changes to record keeping and disclosure procedures. However, if the information subject to these new rules includes family history and blood test results, virtually all medical record keeping would be affected.[18]

Some have suggested that developments in molecular medicine, which lead to routine use of tests for gene products, indicate a broader definition is needed —one that includes at least the results of tests for gene products. If a gene-product test were conducted on an asymptomatic individual for the purpose of determining the risk of developing a genetic disease or medical condition, it would have similar implications for individual privacy as analysis of DNA that codes for the protein.[19] Blood tests to determine the presence of a polipoprotein E (ApoE) illustrate how the presence of gene products is used to predict susceptibility to heart attacks and may also be used as an indication of risk for Alzheimer disease, a late onset genetic disease.[20] If enough were known about the associations between specific gene products and various diseases or conditions so that analyzing DNA for genetic markers for those diseases were to become unnecessary, we would have to decide whether to treat the information from such tests the same as the information currently derived from DNA analysis.

V. FAIR INFORMATION PRACTICES

Once the difficult hurdle of defining private genetic information is cleared, establishing information practices that will adequately protect individual interests is a less formidable task. The GPA requires those who maintain the information in the ordinary course of business (rather than friends or relatives

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18. In fact, an early draft of the GPA incorporated genetic information derived from family medical history into the definition of "private genetic information." Because of the practical consequences of defining private genetic information in such a broad manner, we opted for the narrower definition and protection of the most private genetic information—that which is discovered by analysis of DNA.

19. This is the trend in recent state proposals. *See, e.g.*, Or. S.B. 276, 68th Legis. Assembly (1995). This also would be more consistent with the concern of the Task Force on Genetic Testing, which focused on the implications for genetic testing for clinical purposes. Its broad definition of genetic tests includes the "analysis of human DNA, RNA, chromosomes, proteins, or other gene products to detect disease-related genotypes, mutations, phenotypes, or karyotype for clinical purposes." It does not include family history despite the Task Force's acknowledgment that it can be an important screening tool. Task Force on Genetic Testing of the NIH-DOE Working Group on Ethical, Legal and Social Implications of Human Genome Research, *Interim Document for Public Comment* (available from Task Force on Genetic Testing, 550 N. Broadway, Suite 511, Baltimore, MD 21205).

20. Richard Mayeux & Nicole Schupf, *Apolipoprotein E and Alzheimer's Disease: The Implications of Progress in Molecular Medicine*, 85 AM. J. PUBLIC HEALTH 1280 (1995).

with whom the person might share this information) to adhere to specific informational practices. Those provisions:

- require written authorization by the individual or legal representative before disclosures can be made,[21]
- limit disclosures of the specific information described in the authorization to those named in the authorization and for the purpose noted in the authorization, [22] and
- grant individuals the right to inspect and obtain copies of records containing their private genetic information.[23]

Consistent with the notion that disclosure of private genetic information can have consequences for the individual that may differ in kind or severity from disclosure of other medical information, a general authorization to release medical records is not sufficient to release private genetic information.[24] Disclosure of private genetic information without prior authorization can be compelled only in limited circumstances, such as suits in which the genetic condition of a party is at issue or when the person maintaining the information is the subject of a criminal investigation in regard to such activity.[25]

VI. MINORS AND INCOMPETENT PERSONS

The GPA has sections governing the collection and analysis of samples from minors and incompetent persons.[26] It prohibits DNA analysis of children under the age of 16, even with parental authorization, for any condition that will not be manifest until after the child reaches adulthood, unless there is some effective measure that can be taken before that time to prevent or ameliorate the condition.[27] However, DNA analysis of asymptomatic children under 18 for research may be authorized by parents, provided that access to the results of the child's genetic information is withheld from parents if it reveals a condition that cannot be ameliorated, prevented, or treated while the child is under 18.[28] These somewhat unusual steps of restricting parental discretion protect the privacy of the adult the child will become.

Similar restrictions apply to the collection and analysis of DNA of incompetent persons and the dissemination of their private genetic information. Such analysis is permissible only when authorized by the person's legal

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21. GPA, *supra* note 1, § 111.
22. *Id.* § 112.
23. *Id.* § 113.
24. *Id.* § 112(f).
25. *Id.* § 115.
26. *Id.* § 141-144.
27. *Id.* § 141.
28. *Id.* § 131(c).

representative, and when conducted for one of three purposes: the diagnosis of the cause of incompetency; the diagnosis of a genetic condition that can be effectively prevented, ameliorated, or treated; or the diagnosis of such a genetic condition in certain relatives.[29] Disclosures of private genetic information are likewise restricted to circumstances involving such diagnoses.

VII. OTHER SPECIAL SOURCES OF DNA

Genetic testing may be most useful and most sought after in regard to reproductive decisions. The GPA gives a pregnant woman of any age decision-making authority over her own genetic analysis and that of her fetus, and authority regarding disclosures of the information that is created as the result of such analyses.[30] Having such information may be critical in regard to decisions related to pregnancy. These pregnancy provisions have been deleted from the GCNA. Similarly, obtaining genetic information about embryos that result from in vitro fertilization may be critical for decisions regarding implantation of embryos. To facilitate such decision making and clarify who can authorize genetic analysis or the disclosure of genetic information regarding extracorporeal embryos, the GPA places decision-making authority with the persons who intend to use such embryos for reproduction because they have the most interest in this information.[31]

CONCLUSION

Whatever the ultimate medical benefits of decoding the entire human genome, the private information obtained from DNA analysis will have a profound impact on how individuals view themselves and others. The GPA attempts to establish rules for the protection of individual privacy as curiosity about perhaps the most private and sensitive information—genetic information—is driven by the piece-by-piece decoding of the genome. Because the GPA focuses on privacy and confidentiality of information, it does not address all the policy issues involved in the creation of genetic information. For instance, prohibitions against use of genetic information so as to avoid harm to other individual interests are not included, although these interests have been addressed in other proposals, such as the GCNA, on both state and federal level. We support legislative action to regulate the *use* of genetic information, and the GPA is compatible with these proposals. For all such proposals, however, the key problem is defining the information that is to be regulated. The GPA's definition and its other provisions have stimulated debate as to how

29. *Id.* § 143.
30. *Id.* § 151-2.
31. *Id.* § 153.

we can best protect genetic privacy. Inasmuch as stimulating and enriching this debate was one major reason for drafting the GPA, the GPA is already a success.[32]

32. *See, e.g.*, Neil A. Holtzman, *Panel Comment: The Attempt to Pass the Genetic Privacy Act in Maryland*, 23 J. L., MED. & ETHICS 367 (1995); Wendy E. Parmet, *Panel Comment: Legislating Privacy: The HIV Experience*, 23 J. LAW, MED. & ETHICS 371 (1995); Ellen W. Clayton, *Why the Use of Anonymous Samples Matters*, 23 J. LAW, MED. & ETHICS 375 (1995); Philip R. Reilly, *The Impact of the Genetic Privacy Act on Medicine*, 23 J. LAW, MED. & ETHICS 378 (1995); Michael M. J. Lin, *Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act*, 22 AM. J. LAW & MED. 109 (1996).