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Report to the Department of Energy

DNA Banking and DNA Databanking: Legal, Ethical, and Public Policy Issues

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The purpose of the grant was to provide support to enable us to: (1) perform legal and empirical research and critically analyze DNA banking and DNA databanking as those activities are conducted by state forensic laboratories, the military, academic researchers, and commercial enterprises; and (2) develop a broadcast quality educational videotape for viewing by the general public about DNA technology and the privacy and related issues that it raises. The grant thus had both a research and analysis component and a public education component. This report outlines the work completed under the project.

I. Research and Analysis Activities:

The research component of our study involved both legal and empirical research. We examined two broad categories of DNA banking and databanking: (1) forensically-oriented banking by the state - for example, convicted offender databanks in state crime laboratories and the military's DNA storage program; and (2) clinically-oriented banking - which is generally associated with academic or commercial DNA testing laboratories but which may also be seen to include state newborn screening laboratories that retain

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blood spots. This section of the report summarizes our scholarly work in each category.

A. Forensically Oriented DNA Banking/Databanking:

We began our research on DNA banking and DNA databanking by analyzing all state statutes that authorize or require the establishment of DNA forensic databanks. We also located all relevant administrative regulations and pending bills on DNA forensic databanking, using a combination of manual legal research methods and LEXIS and WESTLAW. We then undertook a detailed content analysis of these materials, describing the relevant state laws on a variety of dimensions, including: (1) the responsible agencies and authorized purposes of the databanks; the categories of offenders covered (including the treatment of juvenile offenders, transferees, and plea bargainers); (2) the effective dates of the statutes and the timing of sample collection; (3) the nature of the samples collected and specific collection procedures; (4) statutory safeguards against sample mix-ups and tampering; (5) the nature of the analysis authorized and quality control provisions; (6) provisions regarding resources and authority to contract for DNA analysis; (7) retention of samples and data and provisions for expungement; (8) provisions regarding databank access by offenders, challenges to the accuracy of DNA data, and the admissibility of DNA data from the databank; (9) confidentiality of DNA samples and data and access to identifiable DNA information by third parties; (10) relationships to other information practices laws; (11) methods of requesting DNA data and the release of anonymous data; (12) penalties for unauthorized disclosure of DNA samples and data; and (13) the role provided for DNA advisory or review committees.

We wrote an article that reports the results of this research, critically analyzed both existing and proposed state DNA forensic databanking laws, discusses the relevant caselaw, and points to several areas where legislative reform is needed. This article, "A Review of State Legislation on DNA Forensic Databanking", was published in the American Journal of Human Genetics (AJHG) 54: 941-958 (1994).

In the next phase of our research, we contacted the laboratory directors or other responsible persons in each of the nineteen state forensic laboratories that had set up or were setting up databanks. We conducted telephone surveys with each of these individuals (except for one, whose lab declined participation), in interviews that ranged from twenty-five minutes to two hours. In conducting the interviews, we used a twenty-seven page questionnaire that contained 145 questions. This questionnaire was reviewed by several survey design experts.

General topics covered in the survey included: (1) the status of DNA collection efforts; (2) the status of DNA analysis efforts; (3) the perceived appropriateness of the current statutory coverage; (4) databank resources and the perceived adequacy of current funding; (5) the retention of DNA samples and data; (6) databank security (including computer security); (7) databank searching; (8) the release of DNA samples and data to persons outside of law enforcement; and (9) the respondents' views on the future of state DNA forensic databanking.

We wrote an article on our findings, analyzed them in their legislative context, and discussed their implications for public policy. This article, "Forensic DNA Data Banking by State Crime Laboratories," was published in the American Journal of Human Genetics (AJHG) 56: 1477-1486 (1995). After analyzing the results of our studies of DNA banking and reviewing the

literature on public policy relevant to this practice, we published a policy perspective of our own, "Setting Standards for DNA Banks: Toward a Model Code of Conduct;" Microbial and Comparative Genomics 1(3): 165-177 (1996).

B. Clinically Oriented DNA Banking/Databanking:

Our research on clinically oriented DNA banking and databanking began with a survey of state newborn screening laboratories regarding: (1) the extent to which they retain Guthrie cards; and (2) the degree to which they permit third party access to blood spots on those cards. While newborn screening laboratories, unlike academically and commercially based laboratories that store DNA specifically for linkage testing or gene mapping purposes, are not technically "DNA banks," we included them in this category because they are clinically oriented and share many of the same features.

We used a five-page questionnaire with nineteen closed-ended questions to conduct this survey. An expert in survey research reviewed the survey instrument. We sent the questionnaire to all newborn screening programs coordinators or laboratory directors listed in the 1990 Council of Regional Networks for Genetic Services (CORN) Newborn Screening Report. The initial mailing in October 1993, coupled with one follow-up mailing, and telephone calls made to those persons who did not respond to either mailing, resulted in a 100% response rate. We wrote an article, "Stored Guthrie Cards as DNA 'Banks'," that summarized and discussed our findings which were published in the American Journal of Human Genetics (AJHG) 55: 196-200 (1994).

Next, we developed a questionnaire to survey commercially and academically based DNA laboratories (all laboratories listed in the HELIX directory of DNA testing facilities) regarding their DNA banking activities.

This survey covered: (1) the scope of their DNA banking activities; (2) their policies and experiences regarding access to DNA samples and DNA test results; and (3) quality assurance matters. It will also cover the extent to which these DNA banking facilities have developed internal written policies and procedures and/or written depositor's agreements regarding: (1) the purpose, form, and duration of sample storage; (2) procedures for the withdrawal of consent to storage; (3) fees for storage, transportation, and testing of samples; (4) when fees are payable and the consequences of non-payment; (5) procedures for maintaining contact with depositors; (6) the need to contact depositors if an improved test or treatment for the disorder in question becomes available; (7) the need to retest samples if improved tests become available; (8) access to DNA samples and DNA data by various persons (including the depositor; his or her physician, spouse/partner, adult children, or other relatives; and other third parties); (9) access by scientists to anonymous samples or data for research use; (10) disposition of samples (for example, at the expiration of the agreed-upon period, if the laboratory ceases operations, or if the depositor dies or is divorced); (11) the liability of the laboratory for the unauthorized release, loss, or accidental destruction of samples; (12) handling of the discovery of non-paternity during DNA testing; and (13) the sharing of profits derived from the commercialization of tests or treatments developed in part from studies of stored DNA. The data generated by our survey were summarized and discussed in an article, "A Survey of DNA Diagnostic Laboratories Regarding DNA Banking," that was published in the American Journal of Human Genetics (AJHG) 56: 1477-1486 (1995).

II. Public Education

The "public education" component of our grant work focused on producing a 30-minute documentary style videotape about the technological, legal, ethical, and public policy concerns associated with DNA banking and DNA databanking. In producing this film, we benefited from consulting with renowned documentary filmmaker, Ben Achtenberg, who was a consultant on the grant.

The film was planned, written, and shot during the spring and early summer of 1994. We finished editing in the fall. We distributed copies of the film free of charge to 800 opinion leaders (legislators, judges, professors, etc.) around the United States.

We then reached a distributive agreement with Fanlight Productions (Boston), a company that is highly regarded for its work in producing distributing documentary films. Since late 1995, Fanlight has been marketing our film.

In 1996, Banking Our Genes won a National Health Information Merit Award (copy enclosed). The American Association for the Advancement of Science rated our video as among the best science education films of 1996. Fanlight Productions expects to keep Banking Our Genes on its active list for several years.

In summary, with support from DOE Grant #DE-FG02-93EER61564, we published five scholarly articles in referred journals, and produced one award winning, broadcast quality, 33-minute science education videotape, Banking Our Genes.