**The Uses of Alternative Dispute Resolution
to Resolve Genetic Disputes
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Final Report^{**}**

Introduction

The Human Genome Project has set aside a portion of its funds to examine the ethical, legal and social impacts of genetics. Not surprisingly, a focus of genetic legal issues has been on lawsuits that have been brought and decided in a number of substantive areas. Additionally, the Human Genome Project has also funded programs designed to familiarize judges with genetic issues that might appear in their courtrooms in order to give them a baseline on how to manage those issues. It is clear that given the contentious issues that can flow from genetic disputes, a range of mechanisms to resolve them should be considered. Some of these disputes, those that make it into the legal system as well as those that do not, may benefit from resolution through a variety of processes which together have been called Alternative Dispute Resolution (ADR).

This report sets out some of the lessons learned while carrying out the study, categorizes potential and actual genetic conflict areas and considers ADR processes that might be used to resolve them or assist in the resolution process. Where possible the report matches up the dispute categories with process that have already or may be used. Finally, the report indicates possible areas for future research. I was very fortunate that a large number of individuals spoke openly to me about their views on genetic disputes and the potential uses of ADR in resolving them. These individuals included judges, government officials, scientists, officials with genetics companies, attorneys, researchers and consumer advocates. I appreciate their insights and assistance. While the report has certainly benefited from these discussions, all statements made are my responsibility.

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Findings

1. Substantial effort was devoted to discussing with individuals in a variety of private and public positions what the potential of using ADR might be in the resolution of genetic disputes. This "Johnny Appleseed" function is important as there was often a questioning as to "what do you mean by genetic disputes" which, when explained—using categories similar to those used in this report—resulted in both greater understanding and enthusiasm. This is in large measure because there is a general view among those approached that genetic conflicts will only increase in number and that once basic principles are accepted through courts, there needs to be ways to resolve them that can be less contentious than litigation. Therefore, it is believed that additional efforts are needed that are devoted to acquainting potential stakeholders or groups that could be involved in disputes with the potential uses of ADR.

2. Genetic disputes are being submitted to courts on a regular basis. Judges are aware of the importance of their having at least a basic understanding of genetics since they may be faced with genetic issues in the court room. This underscores and provides the rationale for the popularity and importance of the EINSHAC-led and other judges' conversations designed to acquaint judges with genetic issues.¹ Discussions with U.S. federal and state judges as well as Canadian federal and provincial judges have led to the conclusion that there is a willingness to use ADR for a number of the categories of disputes discussed below. Judges are willing, and in some cases even eager, to turn disputes over to a mediator or arbitrator prior to judicial review because of their view that these processes may result in a prompt and cost-effective solution.

3. Discussions with academic experts and business and government officials involved in genetics have also led to the conclusion that genetic disputes will increase in number and diversity and that the use of alternative means to resolve disputes either in advance of litigation or in place of it deserves consideration and further use. This is especially true for those issues for which there has already been a decision that established a precedent.

¹ See 36 The Judges Journal (Summer 1997) devoted to Genetics in the Courtroom, and Zweig and Cowdry, "Educating Judges for Adjudication of New Life Technologies", 83 Judicature 157 (1999).

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4. It proved more difficult than anticipated to determine the extent to which ADR processes have already been used to resolve genetic disputes. This was in large measure because ADR organizations such as the American Arbitration Association (AAA) do not classify disputes as "genetic" disputes, but rather categorize them as patent licensing, health care, employment discrimination or commercial cases. This most likely means a number of genetic disputes have been decided by arbitration, although because they are classified differently they are difficult to identify.

5. While mediation and arbitration are the first two processes that often come to mind for individual disputes, independent fact-finding, independent neutral evaluation and the use of court appointed special masters are processes that have a great deal of promise. Courts are often the focus for "dueling experts", and in the genetics area this can be confusing and not likely to lead to the best result. However, if both parties can agree in advance to use a single expert (or group) whose views will be accepted by both parties or if a judge appoints such a person, a significant hurdle and opportunity for confusion on the part of judge or jury can be overcome. How to achieve this remains an important challenge.

6. The difficulty in how to categorize genetic disputes leads to the issue of genetic exceptionalism. A pervasive issue in discussions I have had is whether the fact that a dispute involves genetic information makes it a "genetic dispute" or whether it is, for example, an employment, intellectual property, privacy of medical information, health care or contractual dispute that should be treated under those categories that just happens to involve genetic information. This issue of "genetic exceptionalism" is similar to discussions involving AIDS disputes and whether they should be treated differently from other health care disputes. My conclusion in the genetics area is similar to that reached with respect to HIV. Because of the nature of the disputes, the need for specialized information, the implications and societal reactions, genetic disputes are the same in many ways as other issues but deserve to be treated differently. I have found general, but not universal agreement with this approach.

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Categories of Possible Disputes²

Henry Greeley has categorized genetic disputes into six broad categories into which most human genetic disputes can be placed. His broad categories are used as the basis for categorization in this report. However, the specific types of disputes that fall within each may not be those that he would include. Moreover, as his categories involve human genetics, there are disputes that fall outside that broad rubric and are listed below under other headings. Other legal and policy experts, including Philip Reilly³ and Mark Rothstein,⁴ have also categorized genetic disputes; the issues they raise have been integrated into the Greeley categories.

1. Human Genomes and Identity

This category includes disputes over individual identity, e.g., DNA testing in criminal and civil cases (challenges both to the accuracy of DNA testing, which is now beyond doubt, or to the way in which the testing was conducted or contamination of evidence); privacy issues, including who gets access to data bases; and cloning both for therapeutic or reproductive purposes. This last can result in policy disputes as there is no agreement in public circles as to whether or the extent to which therapeutic stem cell research should be permitted. It also may result in individual disputes as well.

2. Human Genetics and Predicting the Future

This category includes disputes resulting from predictive or diagnostic genetic tests done for insurance, employment and medical care, family reactions to predictive tests (e.g., for Huntington's disease) or requirements for consent for testing for predictive issues. There have already been disputes

² The categories that are used have been adapted from Henry T. Greeley, "Legal, Ethical, and Social Issues in Human Genome Research," 77 Ann. Rev. Anthropol 473 (1998).

³ Reilly, "Legal Issues in Genomic Medicine."

⁴ Rothstein, "Protecting Genetic Privacy: Why It Is So Hard to Do."

over the use of genetic tests in the workplace. The U.S. Equal Employment Opportunity Commission (EEOC) has used mediation to settle one such dispute involving genetic testing by the Burlington Northern Santa Fe Railroad.⁵ Over 30 states have legislation that bars the use of genetic testing for employment purposes, and most states have legislation limiting the use of such testing for purposes of insurance.⁶ Federal legislation limiting the use of genetic testing for private employment purposes is under consideration and will complement an Executive Order that applies to federal workers.

3. Human Genetics and Revealing the Past

Genetic tests can provide information about past actions and consequently can end in disputes over the results of those actions. Examples include the use of DNA to determine paternity,⁷ issues of privacy that result from tests that can affect more than one person (e.g., identical twins, or other siblings) and issues relating to whose consent should be required for the test. Test results also have resulted in employment discrimination or the ability of an individual to obtain health or life insurance. Rothstein comments that confidentiality, "the right of an individual to prevent the re-disclosure of certain sensitive information," is difficult to maintain in health insurance and employment.⁸ As a result of either testing or failure to test for specific diseases, actions for wrongful birth have already been seen. ADR mechanisms may be useful in avoiding long and costly litigation.⁹ According to one survey, the most frequently mentioned concerns about the sequencing of the human genome were privacy violations and discrimination.¹⁰

⁵ See EEOC Press Release May 8, 2002: EEOC and BNSF Settle Genetic Testing Case under the Americans With Disabilities Act.

⁶ For employment information, see the website of the National Human Genome Research Institute which lists 31 as of April, 2002, and The Council for Responsible Genetics which lists 45 states that have considered limitations on insurance. See also Pagnattaro, "Genetic Discrimination and the Workplace: Employee's Right to Privacy v. Employer's Need to Know" 39 Am. Bus. L. J. 139 (2001).

⁷ See Anderlik and Rothstein, "DNA-Based Identification and the Future of the Family: A Research Agenda" 28 Am. J. Law, Med. And Ethics (2002), and Suter, "Whose Genes are These Anyway?: Familial Conflicts over Access to Genetic Information," 91 Mich. L. Rev. 1854 919930.

⁸ See Rothstein, *supra*, note 3.

⁹ See Burke, Atkins, Gwinn et al. "Genetic Test Evaluation: Information Needs of Clinicians, Policy Makers, and the Public," 156 Am. J. Epidem. 311 (2002).

4. Manipulating Human Genomes

There are two principal areas for disputes under this category: cloning and gene therapy. Cloning, a broad term encompasses both stem cell research for therapeutic purposes as well as for reproductive purposes. There have been policy disputes over both, and that can be expected to continue. As a result there may be opportunities for both policy dialogues and regulatory negotiation processes to assist in these disputes. Gene therapy experiments have resulted in individual disputes, one of which was settled.¹¹ Additionally, it was recently reported that U.S. officials have suspended 27 gene therapy studies while they investigate possible serious risks. One of the trials is associated with a type of gene therapy for severe combined immunodeficiency (SCID).¹² If there are adverse events associated with these trials, it can be expected that individuals will seek compensation and that ADR may be useful in that regard.

5. Ownership and Control of Human Genes and Genetic Information

The area of genetic information that has led to a great many disputes involves the patenting or the ownership of genetic information. This covers a number of fields, including the right to develop and market biotech products, the ownership of diagnostic tests and the ownership of genes themselves. The amounts of money can be considerable, and the commercial entities involved litigation in this field is already widespread.¹³ Based on discussions with several attorneys practicing in this area, there are a number of issues for which ADR may prove useful, including resolution of licensing, informed consent, patent protection and appropriate use of cell lines. Additionally, disputes involving issues of privacy and informed consent could also benefit from ADR processes. As many disputes over ownership of genetic material are international in scope, organizations including the World Intellectual Property Organization (WIPO) have developed protocols for the use of

¹⁰ Geller, Bernhardt and Holtzman, The Media and Public Reaction to Genetic Research.

¹¹ Gelsinger v. University of Pennsylvania. This case was also interesting in that a university ethicist was named as a defendant, although he was dropped from the case.

¹² Associate Press, Jan. 15, 2003.

mediation and arbitration in commercial patent disputes that would be applicable here as well.¹⁴

6. Using Altered Molecules for Public Good

Hazardous waste remediation and oil spill clean up have proven difficult to carry out in an environmentally sound way. In both arenas, the use of altered molecules has been offered as a benign and effective way to meet the problems. In some communities concerns have been expressed as to the safety of these approaches. When information has been provided, it often, but not always, satisfies the concerned citizenry. In some cases the use of particular molecules has been challenged, and law suits have been brought to stop the actions. In such situations, ADR approaches may prove useful to resolve the issues.

7. Genetically Modified Food, Food Products and Seed

Where pests have proven to be harmful to food crops, suggestions have been made to genetically alter the crops to make them disease resistant. Where herbicides and pesticides are used, genetically modified crops have been developed so that spraying will not harm the crops.¹⁵ Other issues have involved the planting of genetically altered seed. Disputes have arisen at all stages of the process, from the planting of seeds to the selling of foods prepared with genetically altered foods. Other genetically modified products include medicines and vaccines, feeds and fibers.¹⁶ Controversies have involved, safety, access to the technologies, intellectual property concerns and ethical and societal issues. In addition to feeds, the dairy industry has been challenged for its use of growth hormone and making rennet through bioengineering. All of these have resulted in disputes, and ways are needed to effectively and cooperatively resolve them.

¹³ See Bar-Shalom and Cook-Deegan, "Patents and Innovation in Cancer Therapeutics: Lessons from CellPro" (in publication).

¹⁴ See WIPO Arbitration and Mediation Center. Some members believe there may be other ADR processes that can play a role. Position Paper of the Asian Group and China, Dec. 2001. WIPO/GRTKF/IC/2/10.

¹⁵ See Rodemeyer, Stretching the Rubber Suit, Nov. 2002 for the Pew Charitable Trusts program on Food and AgBiotech.

Possible ADR Processes

This section is divided into two parts, processes that are designed to resolve individual disputes, and those that can assist in the resolution of policy or regulatory disputes. There certainly are ADR processes that have had successful use in other arenas that are not listed here. From among the broader universe of ADR processes, the ones listed are those that offer the opportunity for both use and possible success.

A. Individual Disputes

1. **Mediation**. Mediation involves the use of a third party who assists the parties to a dispute in finding a solution that is acceptable to both parties. Mediation can be voluntary or mandatory, but the outcome is only binding on the parties if they agree to it. Mediation clauses can be inserted into contracts between parties and also can be mandated by a court prior to permitting litigation to go forward.¹⁷ Parties to virtually any of the disputes noted above could consider mediation as an approach to assist in resolving that dispute.
2. **Arbitration**. In arbitration the independent third party, the arbitrator, decides the dispute based on the facts and applicable law.¹⁸ There can be a single neutral arbitrator; a panel of three arbitrators in which each party selects one arbitrator and together they select a neutral third arbitrator; or three neutral arbitrators. A dispute can be brought to arbitration as a result of the agreement of the parties to use it in a specific situation or as the result of a contract or agreement that calls for arbitration to resolve a specific set of issues. Arbitration does not necessarily follow the rules of evidence used in a court, but does operate under specific rules. In most cases, arbitration is binding on the parties; in some, it is advisory. The terms of the arbitration will determine the binding nature of the issue. Before arbitration can be used as a binding approach, courts have determined that the parties must have knowledge of the process and agreed to its use. Intellectual property disputes, suits for compensation for injury caused during gene testing

¹⁶ See Fact Sheet, Genetically Modified Foods and Organisms, Human Genome Project.

¹⁷ See Niemic, Stienstra and Ravitz, Guide to Judicial Management of Cases in ADR at 8 and App. A at 128 ff. Fed. Jud. Center (2001).

studies, bioremediation and specific disputes over genetically modified foods can be resolved through arbitration.

3. Mediation/Arbitration. This combination approach begins with agreement by the parties to first seek the resolution of the issues under dispute through mediation. Arbitration will then be used to resolve those issues that are not resolved through mediation.
4. Independent Neutral Evaluation or Independent Fact Finder. In situations in which there is an issue of fact, an independent neutral can find the facts. The fact finder can be agreed to by the parties or selected by a judge or other trier of fact. In some genetic disputes in which scientific or technical information is in dispute, the use of an independent expert can avoid "dueling experts," which can be confusing in a court proceeding.
5. Master. A master is an independent expert appointed by a federal court under the federal rules of Civil Procedure,¹⁹ to find facts and report back to the court. In some cases, upon agreement of the parties or if ordered by the court, the special master can take on additional functions. The federal courts appoint masters in about 2% of the cases before them in order to address technical issues of fact, provide accountings, administer class settlements and implement and monitor consent decrees. All of these issues may arise from a genetic dispute involving a complex patent or environmental case. While activities in appointing a master are rare, they occur primarily in high-stakes cases that are especially complex and involve highly complex scientific or technical issues. About two-thirds of masters appointed have legal background. Masters can either be experts or generalists. If the latter, they can rely on experts such as those fitting into number 4, above. Based on discussions with individuals who have served as special masters and others who are potential users, the consensus was that masters can be generalists, but should have access to experts in the particular fields or issues

¹⁸ Id.

¹⁹ Rule 53 of the Federal Rules of Civil Procedure. See also Wilgang, Hooper, Leary, Miletich, Reagan & Shepard, Special Masters: Incidence and Activity, Fed. Jud. Center (2000).

under dispute. Managing the system, while being able to have resort to expertise, is considered preferable to an expert on top who does not have the ability to manage the process.

B. Policy and Regulatory Processes

1. **Policy Dialogues.** A policy dialogue is a process in which a facilitator assists stakeholders seeking to reach agreement or a consensus on a policy. The concept of consensus conferences used by the National Institutes of Health and other agencies is similar, but it does not use a third party. Issues relating to bioremediation and policies regarding genetically altered foods would lend themselves to this approach.
2. **Regulatory Negotiation.** Regulatory negotiation has been used to reach agreement among diverse interests as part of the regulatory process. By involving all interested parties or groups, including the regulatory agency, it has been possible to reach agreement on a regulatory solution. In a federal regulatory negotiation, the agreed texts can be published in the Federal Register. This process usually receives approval more quickly than if the more traditional approach is followed—publishing a draft notice followed by a comment period, followed by publication with the possibility of challenge after that. Environmental standards or regulations and those in the environmental health area among others have successfully used this approach. Standards for confidentiality, informed consent and other related issues could benefit from it as well.

Future Research

1. Among the leading areas for disputes involving individuals and entities are bioremediation, genetic testing for employment and insurance (including medical care) and privacy concerns in the workplace dealing with genetic information. Policy disputes in these areas and the opportunity to use regulatory negotiation in their resolution also may increase. Therefore, the potential stakeholders in these disputes should be identified, contacted and acquainted with the possibilities of ADR and how to access different systems. This uses the Johnny Appleseed principle discussed in the findings above.

2. With bioremediation proceeding both for hazardous waste and oil spill clean up, opportunities should be sought to test the acceptability of ADR processes for related individual and policy disputes. The results should be evaluated to determine future use of these processes.
3. If ADR is to be used, several preconditions must be met. First, individuals and entities seeking to use ADR must understand options and how to access the systems. Second, there must be confidence that the ADR professional understands the generic issues involved. This leads to a need to better understand training requirements for ADR professionals and the timing of their training. The approach used by EINSHAC and others for acquainting judges with genetic issues should be studied to determine how elements can be adapted for ADR professionals.
4. Effort should be devoted to working with select federal district courts in which judges have become acquainted with genetics issues and where the court already has developed an ADR program. Federal courts in Baltimore and Washington, D.C., fit that category. As part of this effort, materials should be developed that can be used for ADR training.