THE HUMAN GENOME PROJECT, DNA SCIENCE AND THE LAW: THE AMERICAN LEGAL SYSTEM'S RESPONSE TO BREAKTHROUGHS IN GENETIC SCIENCE

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DR. KATHY HUDSON
National Human Genome Research Institute
National Institute of Health

AARON M. BAILEY
American University Law Review

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P R O C E E D I N G S

MR. BAILEY: Welcome back. My name is Aaron Bailey. I am editor-in-chief of Volume Fifty-one of the American University Law Review. We are very glad to have you all here today, and it's my pleasure and my honor to introduce our keynote speaker, Dr. Kathy Hudson. Dr. Hudson is the Director of Policy and Public Affairs at the National Human Genome Research Institute.

She is responsible for communications, legislation, program planning, and education activities at the Institute. Dr. Hudson has provided focus and leadership in public policy and public affairs issues relating to the Human Genome Project, and she has led efforts to identify barriers, such as genetic discrimination, that could impede the fair and equitable application of genetic information to public health and has led the development of policies to protect privacy and genetic discrimination.

She has written various articles on these topics. Before joining the Genome Research Institute, Dr. Hudson was a policy analyst in the Office of Assistant Secretary for Health at the Department of Health and Human Services. She advised the Assistant Secretary on national health and science policy issues.

Dr. Hudson has a B.A. in biology from Carlton College, in the great state of Minnesota, an M.S. in microbiology from the University of Chicago, and a Ph.D. in molecular biology from the University of California at Berkeley.

DR. HUDSON: Thank you. I'm pleased to be here today. I'm always somewhat ambivalent when I give a talk over a luncheon whether or not there's some conflict between the delectability of your plate and what I have say. Here we go.

What I would like to do is provide a very short overview of the science. The issues that were discussed this morning were quite technical in the legal department and didn't really get at the science. I'd like to provide a little bit of an overview of where we are scientifically and some of the policy issues that are raised by the wealth of information in genetics and genomics that are coming out of our laboratories now.

It has been really remarkable to be associated with the Human Genome Project over the last couple of years both scientifically and sociologically. It almost seems that the Human Genome Project and DNA have become household words. Certainly my mother is able

now to have fairly sophisticated discussions with me about the Human Genome Project, and that's new. Although she's always been extraordinarily proud of me, she really lost touch with what I was doing once I left home and now she's more in touch because of the Human Genome Project.

Some of the examples of how the genome is entering modern culture include cartoons that are appearing in newspapers and magazines virtually daily. DNA is also used to market products. This is DNA perfume.[1] "It's why you have your father's eyes, your mother's smile, and now Bijan's DNA perfume." If you're feeling a little lethargic after lunch you might want to try the RNA-DNA energy and immunity formula to give you that extra boost.

There's even a bar in San Francisco, and actually it's been around for a while—I went to this bar when I was in graduate school—the DNA Lounge. Guess what you drink when you go to the DNA Lounge. DNA alcoholic fruit and spring water. The DNA Lounge may have become a cyberlounge and while you're there you might be able to send a DNA-o-gram. I've become quite fond of these. You enter your message on this web page, your message is then translated into the genetic code and can be sent off as an email to people who then can go back and decode your genetic message.

So, DNA and the Human Genome Project have permeated our culture. What I'd like to do is talk about what is a gene, what is a genome, what's the Human Genome Project really about anyway, and then as a special surprise I'd like to tell you what's special about Gregor Mendel's forehead. You guys all remember Gregor Mendel? He was the monk who had the peas and developed the laws of inheritance.

So, what is a genome? A genome is all of the hereditary material within our cells. DNA is packaged into chromosomes, and there are twenty-three of them, which were imaginatively named chromosome 1, chromosome 2, chromosome 3, and so forth. The chromosomes themselves are made up of DNA, a very simple molecule that has four subunits—A, T, C, and G. So, to sequence DNA simply means to determine the precise order of those letters along the DNA molecule.

Now, if you took the DNA from a single cell and strung it out, it would be about six feet long. There's an enormous amount of material there—3.1 billion letters of DNA in the human genome.[2]

The reason why we sought about sequencing the human genome

1. Dr. Hudson referred to a slide depicting a bottle of "DNA" perfume.
2. *See* Exploring Our Molecular Selves: A Multimedia Educational Kit, *available at* http://www.nhgri.nih.gov/educationkit.

was for a health purpose. The mission of the National Institute of Health, after all, is to improve human health. So, we sought to sequence the human genome in order to understand human disease. In fact, virtually every disease has some genetic component.

Now on one extreme are diseases such as cystic fibrosis, Huntington's disease, and sickle cell disease, where if you have a misspelling in that gene you will pretty much inevitably develop that disease, though some environmental factors may modify the severity of that disease.

On the other end of the spectrum are things like AIDS. Now, we all know that AIDS is caused by human immunodeficiency virus, which is an environmental agent, and yet it turns out that we carry that encode—the docking protein the virus needs to get into human cells. Depending on the spelling of the gene, the docking protein can have a different shape and therefore be better at docking the virus or not as good at docking the virus. People with a particular spelling are largely immune to infection by HIV.

But most common diseases fall in the middle. For such things as diabetes, heart disease, cancer, et cetera, it is not just a single gene that's involved; it's many, many genes interacting with one another and interacting with complex environmental factors that increase the risk for that disease. The challenge is to dissect all this out in order to better understand how to develop new treatments.

Where we want to get to ultimately is at the end, the bottom of this slide.[3] We want to develop new drug therapies—in some cases gene therapies and new preventive interventions—in order to treat disease. We are in the top part of this slide[4] currently, and increasingly with time we'll move down to develop new and more effective treatments.

So, the Human Genome Project was started in 1990, and the flagship endeavor, of course, of the Human Genome Project is the sequencing of the human genome. We didn't start sequencing the human genome right away. We first had to develop the tools, technologies, and know-how to make sequencing fast and cost-efficient. We really started sequencing in earnest in 1999. This was done by an international collaboration of scientists from around the world, the United States, the United Kingdom, France, Germany, Japan, and China. All these scientists, who ordinarily work in a very competitive mode with one another, joined together in an international collaboration in order to get this job done. Together

3. *See* Appendix I.
4. *See id.*

these genome scientists sequenced a thousand letters of DNA every second of every day, twenty-four hours a day, seven days a week.

This is a little cartoon showing the chromosomes and the parts that we had sequenced in various draft or finished forms in March of 1999.[5] Through this ramp-up of the sequencing process you can see how much progress we made by June of 2000.[6] We're very proud of this accomplishment.

In June we completed a working draft of the human genome. It was said this morning that the Human Genome Project was "done" and the human genome sequence was "complete." That's actually inaccurate. We have a goal of finishing the human sequence to a high level of accuracy by 2003.

What we have in hand right now is a working draft of over ninety percent of the genome. About fifty percent of it is in finished form at the present time. We still have some of the hardest bits to do. But, in June, we had achieved a major goal, so we had a little celebration along with our friends from Celera Genomics at the White House, and this made lots of news. Francis Collins, my boss, and Craig Venter, the head of Celera Genomics, were on the cover of Time Magazine.[7]

In the following six months, the brightest scientists from around the world from many, many different disciplines—from computational biology to statisticians—scoured all that sequence.

By the way, all that DNA sequence from our effort was immediately placed into public databases as it was being generated so that anyone anywhere in the world with an internet connection could use that information to pursue their biological questions and scientific research.[8] So, in the following six months after we had cleared the working draft, the scientists scoured the sequence to see what they could learn about it and then together published a scientific paper in the scientific journal *Nature* in February.[9]

From the time that we submitted the paper until it was actually published, we had some time to think about what should be on the cover of this magazine. *Nature* was gracious in allowing us to design the cover, and you can see here that it's an image of the double helical structure of DNA but the image is actually made up of

5. *See* Appendix II.
6. *See* Appendix III.
7. *See* TIME, June 2001.
8. *See* DOE Human Genome Program Research in Progress, *available at* http://www.ornl.gov/hgmis/research/research.html.
9. *See* International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome,* NATURE 2001, 409, 860-921.

people's faces from around the world. [10] We thought this fitting since DNA is about all of us, and human beings as a species.

Scientists sometimes have a sense of humor, and so we developed a scientist's version of "Where's Waldo?" and buried some of our heroes in this picture. Two of them, Watson and Crick, who originally discovered the structure of DNA, are hidden down here in the bottom of the picture. We also put in Gregor Mendel, the pea guy, but unfortunately and to my great dismay, when we actually got the first prints of the magazine—Mendel had been cropped off and so only his forehead is left on the cover.

So what did we find in the genome? I'll tell you a couple of cool things that we found. The first, which was mentioned this morning, is that the number of human genes is much fewer than expected. We had been batting about the number 80 to 100,000 human genes for many, many years based on some preliminary, very rough estimates.

It turns out that we have more in the range of 31,000 genes in the human genome.[11] That's sort of sobering in light of the fact that a little weed called Arabidopsis has 25,700 genes. So how do we develop all of the complexity that is a human from just a handful more genes than this little weed has? There are some interesting explanations for that.

Our genes are more complicated and complex than those found in lower creatures, and that is an area that is ripe for research and exploration.

One of the other interesting things that we found is that the mutation rate in males is about twice that in females.[12] If you want to look at this as bad news, it means that men are responsible for two-thirds of all genetic disease. If you want to look on the positive side, you could say that males are responsible for two-thirds of evolutionary progress.

By sequencing the human genome one can see how related we are one to another. We're a very, very young species and so there hasn't been a lot of time for groups of individuals to diverge from others. One of the findings from sequencing the genome is that we're all 99.9 percent identical at the DNA level.[13]

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10. *See* NATURE 2001, 409.

11. *See* Genomics and Its Impact on Medicine and Society: A 2001 Primer, *available at* http://www.ornl.gov/hgmis/publicat/primer2001/1.html(2001) (giving an overview of the human genome and its impact on scientific research).

12. *See* Genomics and Its Impact on Medicine and Society: A 2001 Primer, What We've Learned So Far, *available at* http://www.ornl.gov/hgmis/publicat/primer2001/4.html (2001) (explaining the information scientists have gained thus far from advances in human genome research).

13. *See id.* ("[t]he order of almost all (99.9%) nucleotide bases is exactly the same

So, the real intention of sequencing the genome was to be able to provide powerful tools for research and discovery, and that's already taking place. When my boss, Francis Collins, cloned the gene for cystic fibrosis in the '80s, it took him about nine years to identify that single gene. Researchers in our intramural laboratories at NIH about three years ago were looking for a gene for a hereditary form of Parkinson's disease, and it took them about nine days using the tools that were available at that point from the Human Genome Project.

And just about a month and a half ago, researchers looking for the gene for Crone's disease, which causes a common form of intestinal disorder, were able to scan through the sequence in the publicly available database and find the responsible gene—the candidate gene—in about nine seconds. So, the advances are really quite accelerated at this point in time.

During the course of the genome project, a new paradigm for how to do large-scale genomics research has emerged, and again that was alluded to, particularly in the intellectual property talks this morning.[14] Novel public private partnerships have been created in which pharmaceutical companies, charities, philanthropies, and the government pool their resources in order to develop large data sets that everyone will need and, everyone can access because there are no IP strings attached.

The advances in genomics have also increased job opportunities for all of you. This graph shows the number of intellectual property lawyers per unit of biomedical research expenditure.[15]

Seriously, advances in genomics hold great promise for the development of drug therapies, prevention, and gene therapies. I'll give you a couple of short examples. We all know when we watch TV we see these direct-to-consumer marketing of drugs about a very happy person on television. You're not entirely sure what they're suffering from but it is clear that the advertised drug has helped them. At the very end of the commercial, the announcer says, in a deep voice, "may cause nausea, dizziness, and death."

In many cases, whether or not a person responds well to a drug, doesn't respond at all to a drug, or has one of these adverse reactions is genetically based. If you can match a person's genetic profile to the drug, then you would increase the probability of giving the person the drug that is right for them. This new field is called

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in all people").

14. *See* Panel One, *supra*, at 371.

15. *See* Appendix IV.

pharmacogenomics.[16] Certainly understanding DNA is going to give rise to all sorts of new drugs. Every pharmaceutical company in the country now has very, very large investments in the area of genomics.

So, we're very optimistic that genomics and genetics are going to revolutionize medicine and lead to new interventions and treatments and cures. Genetics really is the future of medicine. So, while there is good reason to be optimistic, the public is concerned.

In a poll that was taken at the time of the generation of the working draft of the human genome, people were asked, "Would you want information about your disease risk?" and sixty-one percent—more than half—said, "Yes, I would like information about my future disease risk. I might be able to do something about it" or "I just want to have that information." But when asked the question, "Will the Human Genome Project be generally harmful?" nearly half said that it would. So, that's reason for concern. Why are people nervous about the Human Genome Project?

This chart from Vanity Fair magazine is another reflection of public concern. It shows what's "in" and what's "out". Pikachu is out; Harry Potter is in, as kid-cult icons. (But, those of us who are parents already knew that.) And then in the category of "scary science", Dolly the cloned sheep is out and the Human Genome Project is in.

So, what are people scared about? This will be the topic of the panel this afternoon,[17] so I'll try not to step too much on their toes, since they've already warned me that if I go over my time I'm going to suffer severe consequences.

The Human Genome Project, when it was initiated, did something very unique in the history of science. From the beginning, the scientists said, we shouldn't just be out here doing this science, completely removed and isolated from the social and ethical and legal consequences of the new knowledge that we're developing. From the beginning there has been a program to look at the ethical, legal, and social implications of the project, and we spent about five percent of our budget in funding research and policy development in this area.[18]

To illustrate some of these concerns, I'd like to tell the story of a

16. Pharmacogenomics is "the study of the interaction of an individual's genetic makeup and response to a drug." Genomics and Its Impact on Medicine and Society: A 2001 Primer, Dictionary of Genetic Terms, *available at* http://www.ornl.gov/hgmis/publicat/primer2001/dictionary.html (2001)

17. *See* Panel Three, *infra*, at 347.

18. *See* Human Genome Project Information, Ethical, Legal, and Social Issues, *available at* http://www.ornl.gov/hgmis/elsi/elsi.html (stating that three to five percent of the annual budget is devoted to Ethical, Legal, and Social Issues).

family. This is Jane's family,[19] and Jane is down here on the right in the yellow dress with the question mark. Jane's family has a high occurrence of a disease, pre-senile dementia. Folks in Jane's family have learned about a research study in which you can be tested to see whether or not they have a mutation in the gene called Presenilin 1. The family is discussing whether or not they want to participate in this research and whether or not they wish to know about possible gene mutations.

Now, it's important to know that there's no intervention available, so if you find out you have a mutation of the Presenilin 1 gene, it's information about your future health but there's nothing really you can do to modify that risk—at least not presently. Of course the hope is that treatments will be developed. So, the family discusses having this testing and many of Jane's family members, but not Jane, decide to get tested. It turns out that, lo and behold, the affected family members—in blue—who have pre-senile dementia all have the letter G in the Presenilin 1 gene where there should be a C. So, should Jane get tested?

What's Jane worried about? Well, one thing she's worried about is whether or not the test results will affect her ability to get health insurance and keep health insurance. Congress took very important steps in 1996 with the passage of the Health Insurance Portability and Accountability Act (HIPAA) to prevent group health insurers from using genetic information in limiting coverage and denying benefits.[20]

And I won't talk about the details of HIPAA because I'm sure that will be covered in this afternoon's panel.[21] In addition to the federal law, a number of states have enacted legislation on both health insurance discrimination and workplace discrimination.[22]

So, it turns out that Jane is in a group health plan and she is in a state that has effective anti-discrimination legislation for health insurance, so she doesn't need to be concerned about that. But what else might Jane be concerned about? Well, even if someone's genetic information can't be used by their health insurer, just the existence of the information might give rise to some privacy concerns.

I'd like to share with you one case relating to genetic privacy. This case involved clerical workers at a federal laboratory in California. As a part of their employment health questionnaire, they were asked

19. *See* Appendix V.
20. 29 U.S.C. § 1182(1) (2001).
21. *See* Panel Three, *infra*, at 347.
22. *Id.*

(1) whether or not they had sickle cell disease, which requires mutations in both copies of that gene; (2) whether or not they had venereal disease; and (3) whether or not they had menstrual disorders.[23]

Now, question how any of that is actually relevant to being able to be a clerical worker but nonetheless those questions were asked. The employees also had medical exams and samples taken during those exams which were subsequently tested for sickle cell carrier status and for pregnancy. The workers brought suit against Lawrence Berkeley Laboratories, and because Lawrence Berkeley Laboratories is a government entity, they did have protections for privacy.[24]

In the ruling, the court said "it goes without saying that the most basic violation possible involves the performance of unauthorized tests, that is, the nonconsensual retrieval of previously unrevealed medical information that may be unknown even to the plaintiffs."[25] However, my favorite quotation from this court decision relates more to the defense in this case. The defense argued that the health questionnaires provided adequate notice to the employees that the tests were going to be performed and that employee consent was implied.[26]

The employer asked about venereal disease and menstrual disorders, but they did a pregnancy test. On this matter the court opined that pregnancy is not considered a menstrual disorder or a venereal disease.[27] Whew!

So, what else might Jane be concerned about? One of the things she might be concerned about is how her employer will deal with this information. This cartoon represents the crux of this issue. In it, the boss says to the employee, "You're lazy, you're unproductive, and, frankly, you've got a lousy genome." In February, of 2000 President Clinton signed an Executive Order[28] prohibiting the U.S. Government as an employer from using genetic information as a basis of making hiring, firing, or promotion decisions—and, again, that will be talked about a little bit later.

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23. Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260 (9th Cir. 1998).
24. *See id.*
25. *See id.* at 1270 (noting that the fact that the testing was unauthorized made it an even more egregious invasion of privacy).
26. *See id.* (rebutting the defense's contention by stating that questions about a medical condition are wholly different than conducting tests to determine whether the person actually has a condition).
27. *See id.*
28. *See* Exec. Order No. 13145, 65 FR 6877 (2000) (prohibiting federal employers from discriminating on the basis of protected genetic information). *See* Panel Three, *infra*, at 347.

What's important is that the President really did this to set an example for the private sector and for Congress to enact legislation that would be effective in governing the activities in the private sector. But, unfortunately, it seems that that train was already out of the station because exactly one year and one day later the EEOC and the employee union brought suit against Burlington Northern Santa Fe Railroad for having conducted genetic tests on its employees without their permission or authorization.[29] Commissioner Miller will talk more about this case in his panel.[30]

So, the question at the moment is will effective legislative solutions be found to the problem of genetic discrimination? Currently there are about 900 genetic tests that are either offered clinically or are in development. That number is only going to go up, and genetic testing is going to become more and more a part of routine health care. What's going to happen with that information? Who will have access to it? How will it be used? These are important questions.

Certainly Congress has been paying attention to this issue for a number of years. Senator Jim Jeffords (I-VT), who was then a Republican, and Senator Tom Daschle (D-SD) wrote an article about some of these policy issues, which indicated Congress's concern.[31] After Senator Daschle became the Majority Leader in the Senate, his very first press conference was on the topic of genetic discrimination.[32]

At the press conference Sen. Daschle said, "We're here to say we're through waiting. It's time for our laws to catch up with our science. We can't take one step forward in science and two steps back in civil rights."[33] We're optimistic that Congress is going to move forward in this area and we were particularly pleased when President Bush a few weeks later indicated his support for genetic anti-discrimination legislation both in health insurance and in the workplace setting,[34] and we're looking forward to seeing and working with the administration to develop the details of those policy initiatives.

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29. Bhd. of Maint. of Way Employees v. Burlington N. Santa Fe R.R. Co., 2001 WL 788738 (N.D. Iowa 2001).

30. *See* Panel Three, *infra*, at 347.

31. *See* Tom Daschle & Jim Jeffords, *Political Issues in the Genome Era*, SCIENCE 2001 921, at 1249-51.

32. *See* Press Release, *available at* http://daschle.senate.gov/~daschle/pressroom/releases/01/06/2001607F03.html (2001).

33. *See id.*

34. Adriel Bettelheim, *Cures May Arise From Genome Mapping, But Congress Anticipates Headaches*, 2001 CQ WKLY., 1505 (discussing George W. Bush's July 23, 2001 radio address during which the president called on Congress to ban the use of genetic information in the areas of employment and insurance).

So, Jane is a federal employee, and is thus protected by the Executive Order. What else might she be thinking about? Well, it turns out that Jane is married to this guy, Harold, and she has two young children. Harold has decided to file for divorce and he also wants custody of the kids.

Harold is aware of the genetic testing for Presenilin 1 and he has gone to the court and argued that if his wife has a mutation in the Presenilin 1 gene, she will be an unfit parent and therefore he should be awarded custody of those children. And these are actually real-life cases. There have been several of these.[35] In one case that I'm aware of the mother actually left the jurisdiction of the court with her children to have genetic testing. Of course it's a separate issue of whether or not having a gene mutation that predicts future health risks in currently healthy people should be considered in custody decisions.

DNA is being used in a number of ways in the courtroom; to exonerate the innocent and to convict the guilty. What future uses might law enforcement and the courts have for DNA? One of the issues that is of high concern to us is the use of DNA as a high-tech form of racial profiling. You heard the gentleman from the forensic lab talking about probabilities based on DNA of an individual being from this race or that ethnic group.[36]

We're concerned about whether or not knowledge of genetic variation, which is an active area of inquiry for us, will reduce prejudice or serve to reinforce it. Many are fond of talking about how similar we are, that we are one large extended family, and yet at the same time in the forensics literature there are a number of articles now appearing about DNA-based racial profiling.

This is an excerpt from a recent paper which states, "It is useful to investigate the power of such an approach in the DNA profiling system to discriminate between the ethnic groups involved in the suspect population."[37]

We have a number of challenges, I think, in how DNA is used in the courts, how it's used in law enforcement, and how it's used by other social institutions outside of the medical context.

I'll just end where I began. I made the statement that the Human Genome Project and DNA have almost become household words,

35. *See generally* Mark A. Rothstein, *The Use of Genetic Testing for NonMedical Purposes*, J.L. & HEALTH 109 (1994-95).

36. *See* Panel Two, *supra*, at 419 (statement of Dr. Samuel F. Baechtel).

37. *See* A. Lowe et al., *Inferring ethnic origin by means of an STR Profile*, FORENSIC SCI. INT'L (2001).

and yet it's our hope that genetics will have more meaning for people than is shown in this cartoon;[38] a technological advance on par with programming one's VCR. We have developed an educational kit to help people understand what genetics means, and you can access it online at www.nhgri.nih.gov/educationkit.

So, with that I will conclude and thank you for your attention and answer any questions you might have.

SPEAKER: I have a question about the term "racial profiling." Would you consider it a form of racial profiling if an eyewitness describes an assailant as being of a given race and, if not, why do you use the phrase for DNA indicating when someone is of a given race?

DR. HUDSON: I think the individual is identifying the assailant based on observable physical characteristics. The understood meaning of eyewitness identifying the suspect as being African-American is probably related to their skin color and perhaps their hair texture, so those are visible, observable characteristics that would be relevant to an eyewitness testimony.

I am unaware of any DNA sequence information that would reveal observable characteristics that would be pertinent in that same way.

SPEAKER: Rare blood types?

DR. HUDSON: Rare blood types—well, we can talk about that, but a rare blood type is not going to help law enforcement limit their possible suspects. I'm talking about observable characteristics and the notion that you would use DNA information to say, "Aha, my suspect most likely is going to look like this."

SPEAKER: Well, in the U.S. the HLA haplotype A9-B54 is found almost exclusively among Asians.

DR. HUDSON: Again, it's a nonobservable characteristic that would help you limit the suspect population.

Other questions?

SPEAKER: When we talked about DNA in the criminal justice system this morning, we only talked about it as an identifier, and I think that to the extent that that has been a complex issue for the criminal justice system to deal with, it's going to pale in comparison to what we're going to have to deal with when the advent or the purported advent of behavioral genetics begins to enter the criminal justice realm for things like defenses to—in death penalty cases or, to take it a step further, predisposition to commit certain crimes. How far away are we from that problem—and I do think it's a problem.

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38. Dr. Hudson showed a cartoon depicting a man watching a television report which stated "Scientists have cracked the genetic code." The man watching the television program stated in response, "Great, I can't even program my VCR."

DR. HUDSON: Yes, so, behavioral characteristics are even more complex than most complex diseases in that there will certainly be and certainly are genetic and environmental factors to our behavior. So, the ability to be able to genotype a person and be able to say "Aha!" this person will behave in this way in these circumstances is a zero.

I believe I recall a presentation to the Secretary's Advisory Committee on Genetic Testing about this issue and about to what extent would we—if we develop this global database of all systems in order to—I'd be able to identify people who had committed crimes ostensibly. What other uses would that information be used for? And I think that's a very troubling question.

If we're going to use that and very pseudo science and say, "Well, let's look at all the American population and then let's see if we can identify those people who are most likely to have behavior S, Y, or Z." I think we get into very significant civil rights issues very quickly.

SPEAKER: However, none of us are. So, even though you may have this wonderful science one has to do a lot to be aware of the education of this new information, and they can talk about screening people as part of the criminal justice system or screening them as they try to enter the United States. They've already limited the population that you're looking at.

DR. HUDSON: We have been very sensitive to these issues and are gratified that discussions such as the one that's happening today are occurring all over the country. As we set our new goals for what we are going to do now that we've got the sequence of the genome, one of our major activities is to look at places in the genome where one individual varies from another in order to find those rare variants or common variants that are responsible for increased risk of disease.

And we understand that as the science reveals that at DNA position 2773, some people have a T and some people have a C, how that information is used and interpreted is a significant source of concern for us. We've been trying to convene people who can help us think through what we need to do now in order to prevent some of those misuses down the road. I appreciate your concern.

SPEAKER: Research and third-party issues with the genome being sequenced, someone might do a research study, give out information about a brother, sister, mother, something like that, and in turn give their DNA. How do you see the impact of the human genome in protecting third parties from having information revealed about them or used without their knowledge, and should—and I'm very much in favor of this—legislation be in place to protect third-party

issues with the genome?

DR. HUDSON: It's a very important question. The principle, the underlying principle, is that when somebody enters into a research protocol, they are asked to give their voluntary informed consent indicating that they understand what's going to be done. Well, the fact of the matter is that my DNA is not just my DNA. It's my family's DNA. It's related to my sons. It's related to my mom. It's related to my sister. So, in genetic studies, very frequently, individuals who are asked to participate are asked to have conversations with their families about these issues, but the bottom line is that because I'm an autonomous human being, if I want something done with my DNA, I still get to make that choice for me. So, the extent to which my family members, who may be opposed to learning this information or having me learn this information, the extent to which they would be considered subjects in a research protocol is an active area of debate at the present time. There's a National Human Subjects Research Protection Advisory Committee who is struggling with this issue of third-party and whether third parties constitute human subjects. Its unclear exactly where that's going to come down at the present time. I think we do have to be concerned about the consequences for family members, but to ask that family members consent for an individual to participate in research actually undermines the rights of that individual because what if everybody says no? "I want to do this." So, it's an interesting balancing act and a very active current topic of debate.

No more questions? I thank you very much for your attention.

MR. BAILEY: All right, we're going to break now. We'll reconvene at 1:45.

[WHEREUPON, A RECESS WAS TAKEN]

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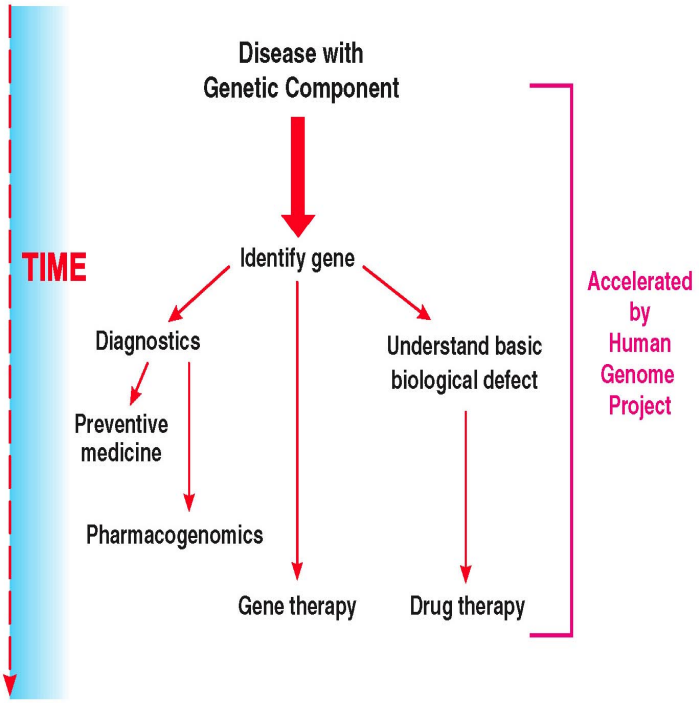
APPENDICES

APPENDIX I



APPENDIX II