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Robert Gellman

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WASHINGTON PERSPECTIVES ON GENETICS AND PRIVACY

*Robert Gellman**

Thank you. Let me offer a couple of introductory comments. First of all, I'm chief counsel to the House Subcommittee on Information, Justice, Transportation, and Agriculture. The chairman of the subcommittee is Gary Condit from California. I am principally an information and policy lawyer dealing with issues like freedom of information and privacy, and that's effectively what brings me here today. Let me say that I'm not speaking on behalf of the subcommittee or any of its members.

I'm going to cover a variety of topics. Hopefully, eventually it will become clear where I'm going. Where I'm going to start — I'm from Washington, it's April 15 — I'm going to start in your wallet. Sometime take out your wallet and take a look at your driver's license.

A driver's license is a very interesting little document. It's got your name, it's got your address, it's got your sex, it's got your height and weight, it's got your age and your date of birth. It's probably got your social security number, depending on the state you live in. It has medical information about you. It says whether you wear glasses or not.

It may say whether you're diabetic or whether you have epilepsy, depending on, again, what state you're in, what diseases they happen to list on your driver's license. It may indicate whether you're an organ donor or not. It also may have a picture. Most licenses these days do have pictures. Some states have digital pictures, which are even more interesting.

Your driver's license is a gold mine of personal information. That's a lot of information I know about you just from your driver's license. Most states sell this data to anybody. Who buys it? It's principally used by direct marketers.

Now, take a look at this information all over again and see how valuable it is. Suppose I have a catalog of big and tall clothing, who do I want to send it to? How am I going to find my market? Well, they're not going to send it to me. But I can go through the driver's license information and pick out people of a certain height and weight, and they're the ones I'm going to send my catalog to.

Suppose I am selling glasses or contact lenses. I can get a list of every potential customer in the state simply from the state government. Suppose I'm selling insurance policies aimed at people who just turned sixty-five. Well, if I want a list of people who turned sixty-five on April 15th, 1994, I can get that information from the state.

There is other information that can be calculated or figured out from the information that's there. For example, if I have a digital picture, I can at least, in principle, rather easily determine your race, automatically through a computer. I don't have to look at it, but I can just do some kind of scanning process and extract the information that way, and there will be other information that I can derive from looking at a picture of you.

Some of the information on driver's license is genetic information. Your sex, your weight maybe, your vision perhaps. The medical diagnoses about you that are on your

*B.S., University of Pennsylvania, 1970; J.D., Yale Law School, 1973.

driver's license may, in fact, be genetic in part. Whether you're an organ donor, is that genetic information? Well, maybe there's a gene for altruism. We don't know that yet.

Driver's license records are a basic source material for America's vast junk mail industry. This is where they get your name in many instances. But it is by no means the only place they get your name. It's a directory of almost everyone in America over the age of sixteen, because virtually everyone in America over the age of sixteen has a driver's license.

This information is combined with other information available from the state and private sources and sometimes from the individuals themselves. There is a tremendous demand — I could go on for an hour just talking about what direct marketers do and how they collect information. I'm just trying to focus here on medical data.

There is a lot of information about you, medical data, that is sold by direct marketers. There are mailing lists. I'm going to give you a couple of examples. You can go out today and purchase a mailing list, that includes 2.7 million hypertensives, 226,000 angina sufferers, one million diabetics, 3.5 million arthritics, one million heavy antacid users, and so on. We're just scratching the surface here.

A lot of this information actually comes from individuals directly. The direct marketers generally do not have access to your medical records, but they get the information from you in a variety of ways. Have you ever filled out a survey in exchange for some coupons and free products? They ask you, does anyone in your family have diabetes. You check the box, this goes into a computer somewhere and they sell your name. Every box you check, you're on another list.

This information comes in other ways. If you get a coupon for a hay fever remedy and it's got a place for your name and address and you write your name and address in, your name goes on a list. Have you ever called an 800 number or a 900 number to get information on a particular product that tells something about you? Any time you call an 800 or 900 number, whether you give them your name or not they know who you are, because they can record your phone number, and they know where you're calling from.

If you call a number for hay fever information, they assume you have hay fever. If you call a number for some other medical product or any kind of consumer product, they know who you are. Johnson and Johnson recently had an 800 number where they were providing information on incontinence pads, adult incontinence pads. They sold the list of callers.

My point here is that there is a strong demand from marketers and perhaps from others for health data. The demand is being met, at least in part these days, through existing sources, some of them other places. If there were better data available, that data might be even more valuable to marketers who want to find people to sell goods and services to.

That's just background. I want to talk a little bit about some of the work that we've done on the subcommittee about genetic information. In 1992, we had a hearing as part of some of our general work on domestic and international privacy issues at which we took a look at the ELSI program — the Ethical, Legal and Social Implications Program of the Human Genome Project.

The committee's concern was a direct outgrowth of general concerns about the increasing creation, use and maintenance of personal information. The driver's license is just one example of how that information can be used, how it is passed around, how it is bought and sold, and how it is used in data banks in combination with all kinds of information

about you.

Obviously — and this has been the topic of discussion here today — the growing ability to recognize new and specific human characteristics through genetic tests was what we were looking at. What is going to happen when we add this kind of information, a new kind of information in some ways and in some ways an old kind of information, what happens when we add this to the mix of personal information that's available about you.

We may get information on propensity to disease. We may get information on your predisposition to engage in particular kinds of activities or behavior. Is there a gene for risk taking, is there a gene for loyalty, is there a gene, as I said, for altruism? We don't know, but perhaps there is.

There have been reports that there are genes for alcoholism or for homosexuality. I don't know whether those are really authoritative studies, but they have been reported in the press. Genes may indicate whether you are predisposed to exposure to particular kinds of chemicals. Perhaps you shouldn't be working in a battery factory if you are.

Your genes may indicate whether you have particular kinds of abilities, whether you will be good at math or whether you'll be good at writing. How will this information be used? What are the rules? That is a key question with respect to all of this information.

How will this information be used in employment? How will employers be able to use this kind of data to select employees? We already have a law called the Americans with Disabilities Act (ADA) that provides some kind of limitation on how employers can use health information in making employment decisions. Is genetic information the same kind of health information covered by the ADA, or is it a different kind of information?

Can I distinguish among my potential employees on the basis of those that I think will be loyal to my company or not? Can I use any of this information to protect employees? Can I allow somebody who is predisposed to be affected by lead to work in a battery factory? It may be in everybody's best interest not to allow that to happen. This is by no means a one-sided issue.

We have just had a very nice discussion about some of the problems with insurance. How will we allow this information to be used for life insurance or health insurance? Perhaps health reform will save us from the preexisting condition problem, but perhaps it won't.

How will this be used in education? Will we begin to sort through students using genetic tests? Will we say this is a student who will be good at math or this is a student who will not be good at math and put them in different classes on the basis of their genes rather than on the basis of their demonstrated abilities.

Will this lead to discrimination? We've already had a discussion of the variety of ways in which people could be discriminated against on the basis of their genes. The conflicts within families and with physicians that are presented are very serious problems and we don't know what to do about them.

And what happens when this information gets to your bank or your credit company? We already see that the direct marketers are using some of this information. What happens when they start marketing on the basis of genetic information?

"Your child has ten percent less ability than the average child in mathematics. Would you like to buy a fancy calculator, would you like to buy an encyclopedia?" The possibilities

are endless and very scary and very upsetting. There are no rules. There are no rules on how direct marketers, for example, can use information.

All the information that your state is selling in driver's licenses is fair game. Anyone can use that information, buy it and sell it as they please and combine it with other data. If genetic information is not controlled in some way, the same thing can happen.

The subcommittee issued a report called designing genetic information policy. It's House Report Number 102-478, for those that are interested. The focus of the report was on how we make decisions in this area. How do we regulate, how do we control this information? How do we decide what uses are appropriate and what uses should be prohibited? The only mechanism that we have today that's looking at any of these issues is the ELSI program as part of the Human Genome Project.

And the ELSI program, and let me say that all the people that I know who are working with ELSI program are good people, thoughtful people, who are hard working and are very effective in what they're doing in ELSI; but, the ELSI program is not doing what we need. I'm criticizing it for failing to do something that it was not designed to do. It's not a policy making organization. It doesn't have the means to make policy recommendations.

What it is doing is funding research, a lot of which has nothing to do with these narrow information issues, but it's funding research, very nice papers done by very thoughtful people, all of which sit on a shelf somewhere and have nothing to do with the policy process. There is no policy process.

The Congress doesn't have the time or ability right now to look at this issue and say, here's how to balance off all of these concerns. Here is how information should be used in employment or insurance. This is not an issue that the Congress is capable of dealing with at this stage.

We need somebody to look at these issues, to weigh the different kind of alternatives and come up with some recommendations. We may need legislation, we may need executive actions, we may need the states to do things, we may need the private sector to do things.

I'm not sure I know what the answers are. As a matter of fact, I'm sure I don't know what the answers are. If I knew what the answers are, I would have said, these are the answers, rather than saying that we need to set up a process to give us answers. That's what's lacking.

That's what the committee recommended in the 1992 report. We recommended that an advisory commission be established by the Department of Health and Human Services and the Department of Energy, both of which are running the Human Genome Project. We said that the existing ELSI program is very nice and should be used as input to a policy making process.

The key requirements for a genetics information policy organization are, first of all, that it should be broadly based. This information that we're dealing with will have tremendous impacts throughout society. It will affect insurers, employers, and schools. It could affect almost every aspect of society in one form or another. Not just its social impacts, its privacy impacts, its economic impacts. It goes all over the place.

We need to have a broad-based group of people take look at this issue. We need to have businessmen and labor unions represented. We need to have students and teachers. We need to have people from disease advocacy groups. We need to have ethicists. We need

to have lawyers. We need to have lots of people. We need a very broadly based organization to wrestle with these problems.

The second requirement for a commission is that it should be independent. The ELSI program is very deep within the bowels of the bureaucracy. For the ELSI program to make a policy recommendation, that recommendation would have to get out of the ELSI program and into the National Institutes of Health. From the National Institutes of Health, it would have to go to the Assistant Secretary for Health, then to the Secretary for Health and Human Services, then to OMB, then to all the other agencies, and anything that survived that process would be useless.

What we need is for someone who is independent of the political process to be able to make recommendations directly to the President and directly to the Congress without having to filter it through the bureaucracy. That was essentially the recommendation that the committee made.

We need to get rules in place before the uses of information become institutionalized. Let me give you an example. We have very few privacy laws in this country that protect meaningful kinds of records, but we do have a law that protects the privacy of your video rental records. This is known popularly as the Bork Bill.

When Judge Bork was nominated to the Supreme Court some years ago, an enterprising reporter went to his video rental store and asked for a lot of the movies he rented. It turned out to be really boring, he only rented John Wayne movies, but people were outraged that this question was asked and answered.

And Congress passed a law to protect video rental records. How protected are they? That's a story for another day. It's not the greatest law in the world, but it's not bad. That is, if you care about video rental records while your medical records and your insurance records and your employment records are unprotected.

Be that as it may, while this bill was going through the Congress, people came forward and said, video rental records are just like library records. We're trying to protect people's exercise of their First Amendment rights, and no one has a right to know what videos you rent and what books you read. How about if we expand this bill to cover library records? It's the same policy.

The FBI came in and said, no way. If you expand this bill to cover library records, we will kill it. And a decision was made by those who advocated this bill that we would take what we could get. The reason that the FBI cared about library records is it had a program called the library awareness program. The FBI went to libraries and sought information about people who borrowed books. The FBI said, if you take away our ability to do this, we will be unhappy.

The lesson here is the FBI does not use video rental records. It's a relatively new kind of record, and it's not very useful for law enforcement purposes. So when someone tried to put a law in place that restricted the use of these records before usage became institutionalized, they succeeded. When someone tried to cover an existing kind of record for which people had a vested interest, that did not succeed.

Right now, by the way, there is a bill floating around Capitol Hill that has passed the Senate and is likely to pass the House in some form next week that will restrict the ability of states to sell driver's license information. There will be a list of exceptions in that bill as

long as your arm, because there are many institutions who use driver's license records. I'm not just talking about direct marketers, but law enforcement agencies, insurance companies, banks, lots of people.

Once records are available, people plug themselves into them and such records become vested interests. In turn, people will fight any restrictions brought against such interests. This is a problem that I anticipate will happen with genetic information if we don't get out in front of it.

The recommendation that we made for an ELSI commission has gotten nowhere. The history of the recommendation is all tied up in the closeout of one administration and the start of another.

There are lots of other biomedical ethics issues, some of which were touched on here today, that are just as complex and that are related to genetics. These involve the intersection between medical information and medical science and the way we live our lives. There are broader recommendations that have been floating around for some kind of general biomedical ethics commission, institution, or mechanism. Perhaps some day something will come out of all of this, but so far I have nothing to report.

However, rather than end on a totally pessimistic note, I do have half a loaf to offer or perhaps half of a half of a loaf, because it hasn't happened yet. I'm working today on a bill, a federal bill to protect the privacy of medical records. This is part of health reform.

Health reform legislation is moving around Capitol Hill. The legislation has been referred in part to the subcommittee I work for, and we have taken responsibility for coming up with some kind of a privacy piece. Everybody believes this is essential because health reform is making the use of medical information even more important than it is today.

Medical records today are not confidential. I don't care what the law in your state is, your medical records are not confidential. There are at least a dozen major institutions that use identifiable medical records every day to carry out their function. You don't know about it. You don't have the right to say no.

What you tell your doctor is not necessarily confidential. It can go to any of a number of different institutions. We believe that there's nothing you can do about that. However, what we can do is offer people fair information practices.

But we can have rules defining the rights of patients and the responsibilities of record keepers. The law can define how information can be used, and the procedures and the standards under which it can be disclosed to other people in a way that will balance your interests with the interests of other significant institutions that, in fact, legitimately require this information in order to carry out their law enforcement function or their public health function or their health research function or their cost containment function.

The legislation that we've introduced is HR 4077. Those of you who are denizens of the Internet can find a copy of the bill and a bunch of explanatory materials on the net available from CPSR.ORG. The path is CPSR/privacy/medical. And if that doesn't mean anything to you, don't worry about it. Find someone who knows how to use the net.

If you want a printed copy of the bill, it's available from the House document room, and the phone number there is 202-225-3456. I have two copies of the bill with me, I'll be glad to leave them with somebody.

Mr. Cooper: Leave them with me.

Mr. Gellman: It's a 78-page bill. It's not something that's short. The premises of the bill, and I'm not going to describe it in great detail because I don't have time, are that there are major gaps in existing law. We have a patchwork quilt of laws. There is no general federal law protecting your medical records and the law in states vary tremendously from state to state.

Pennsylvania may not have a law at all, I was advised at a lunchtime conversation. A few states have semi-modern laws. Lots of states have old-fashioned laws that answer very few questions. And finally there seems to be a recognition in the medical community that we need a uniform federal law. The only way to deal with the interstate transfer of information, the only way to permit the efficient transfer of computerized information, the only way to support the use of electronic data interchange, is to have a uniform federal law that will support the flow of data. We need common technical standards and common policy standards so that the same information can be used in the same way in various states.

The bill we proposed, and it's by no means a final product, is now in the first draft. It will be consistent with any form of health reform, be it single payer or alliances or any mixture of anything, any kind of network, any kind of system, no matter how the information is to flow we've written something that is completely neutral, completely independent of a particular health care structure.

The legislation offers a couple of features. First of all, it offers comprehensive rules for health information that will follow the information wherever it is disclosed. We will not only cover the primary collector of information — principally the physician or perhaps the insurance company — but other people information is disclosed to. Information will only be permitted to be disclosed in accordance with the law and the secondary users will have obligations under the law.

We will no longer have a situation which is common today where the doctor may be subject to legal or ethical restrictions on what can be done with information, but when that information goes to the insurance company — typically with your consent — the information is unrestricted in how it can be used.

Second, we will give patients a right of access to their records and a right to correct their records. Third, one of the features of the bill that's being debated now has got to do with informed consent. We are moving away from the model of informed consent for disclosures of records. Right now when you go to your doctor, typically you sign a form that basically says I consent to the disclosure of my medical information to anyone, any time, any how. It's a notice that protects the doctor's interests.

What we are trying to do is to say we don't want people to sign those statements anymore. We want to set the terms in the statute the terms under which information can go to insurers and that states how those insurers can use the information. Informed consent is like the Holy Roman Empire. The Holy Roman Empire, as has been commonly said, is not holy, Roman, nor an empire. Well, informed consent in the context of information disclosure, is not informed and it is not consensual. People don't know what they're signing. People don't know what the consequences are. We can do a better job by setting the terms in a

statute rather than letting individuals sign forms that are written by doctors and by insurance companies to protect the interests of the doctors and the insurance companies and not the interests of the patient.

The bill includes several enforcement mechanisms, criminal penalties, civil penalties, civil money penalties, and an alternate dispute resolution. It has requirements for security and a variety of what are relatively standard, fair information practices.

The bill's prospects are uncertain at this point. We're very hopeful if health care reform gets all the way down the track — and your guess about that is just as good as mine — there's a good chance this will be a part of it. What the bill will look like when it comes out the other end of the process remains to be seen. We're working hard.

The bill has lots of problems that we're working out. If any of you take a look at it and have questions or solutions to problems or find things that haven't been discovered, give me a call, I'm glad to hear about it.

Let me just conclude by saying what I've tried to do here today is present, from the prospective of information, a series of overlapping policy problems that spin around medical information. Your driver's license, genetic information, and medical information, contains a lot of overlapping information, and offers many of the same problems. There are very few restrictions anywhere and the availability of new kinds of personal information will put tremendous pressure on existing institutions which do a rotten job right now of dealing with the personal information that is currently available.

Existing problems with the sale and transfer of information without your knowledge and without your consent will continue, and if we don't do something about it, it's going to get worse. If we don't get ahead of the genetic information problem pretty soon you're all going to be seeing junk mail coming to your homes that's going to say, we know you have this medical condition, we know your child has this deficiency, we want to sell you goods and services based on that information. I don't think people want that. If we don't do something about it pretty soon, that's what's going to happen. Thank you.