"Genetics and Legal Institutions"

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appellate court judges, six of us previously practiced law. None of us has a background in the natural sciences.

Second, as you well know, genetic research promises not a few, but many, changes in many different fields of the law. In the field of genetics, every month seems to bring a new discovery or a new medical implementations of earlier discoveries. Changes in our understanding and ability to make use of the genetic code already promise to affect family law; patent law; the laws protecting privacy; and our regulation of safety, the environment, health care, insurance, and employment. And we are only at the beginning.

Third, law itself is complex, not only because it comprises all these different fields, but also because relies upon a variety of different mechanisms. The many forms of law relevant to genetics range from professional rules of ethics governing, say research or hospital care, to local, state or federal regulatory rules, to jury-administered civil standards, to judge-administered common laws, to civil and criminal statutes, to federal and state Constitutions. Legislative enactments and judicial decisions are only two of the several ways in which law reflects social policy changing in light of scientific developments.

Fourth, legal institutions react slowly. Change in the law ordinarily takes place after the event in light of known circumstances, rather than in anticipation of what is to come. The principle of restraint is built into nearly every aspect of the American legal system. Our Court's powers, for example, are limited by the fact we can only act on live controversies brought before us. Congress, in turn is limited by our review, the President's veto, and many other aspects of our political system. In borrowed scientific terms, American legal institutions require an enormous amount of "activation energy" before anything happens.

Given these background circumstances, you might well ask how our Court's judges, nine lay men and women, considering any one of many possible different scientifically-significant legal issues in various fields of law, can obtain a proper understanding of the relevant science and its significance. Of course, traditionally some have believed that we need not know science but only law to make decisions. This view is increasingly unrealistic. Since the implications of our decisions in the real world often can and should play a role in our legal decisions, the clearer our understanding of the relevant science, the better. But, I repeat, we are not scientists; hence the dilemma.

The ordinary way we learn the details of relevant technical subject matter is through "briefs"—that is, the legal papers filed by the parties and other interested groups in our Court. When four years ago we considered whether the Constitution provided a right of a terminally ill patient to physician-assisted suicide, we received approximately 70 briefs including numerous amicus curiae (friend of the court) briefs, each twenty to thirty pages submitted by groups who were not parties to the case. These groups included medical associations, psychiatrists, nurses, representatives of the physically and mentally disabled, hospice workers, religious associations, scientific organizations, law professors, and others. Sometimes a group would split with different parts taking different sides of the case.

This is not the only way we can learn. In our first major internet case, for example, our library prepared demonstrations that helped assure each of us that we knew how to use the net and understood the technical matters at issue. And of course Justices do not live in vacuum; we read newspapers or magazines or books just like any citizen. But briefs are more directed to the precise questions we face. And, in my view, briefing of the relevant medical features of the "right to die" case worked well. Seventy briefs, though requiring a week or so to read, is not too many, at least if we receive that number only on rare occasions. The amicus briefs were not repetitive. At their most useful, they told us not about the law, which the parties to the case discussed, but they told us how our decision, along with the relevant medical practices, might affect the groups, for example, of doctors, nurses, or hospice workers, whose experience they reflected. They presented the kind of predictions of consequence that, in my view, we need.

But most important was the timing. The "right to die" issue did not come to us at the first sign of controversy. It came after many groups and individuals had reflected carefully upon the implications and impact of the legal issue. The relevant public policy issues, including our decision's likely social impact, had already been previously debated at length, in various public forums, often by representatives of many of the same groups that had submitted briefs. In such cases our Court rides the coat-tails of an existing public debate. A select committee of the House of Lords in Britain had previously written a thorough report about the "right to die," after extensive hearings where evidence, including empirical evidence, had been presented. A New York State commission had done the same. The matter had been debated in Australia and in Oregon as well as in the Netherlands. The result

of the earlier discussion and debate was not agreement about the proper result; but it was agreement about the nature of the question and upon many of the relevant parameters.

This kind of agreement — the kind that focuses issues and excludes unreasonable possibilities — is critically important. You may know of the physicist Wolfgang Pauli's reply when he was asked whether a certain scientific paper was wrong. He said, "Certainly not. That paper is not good enough to be wrong." Those are the papers that this kind of preparation can, and must, exclude. The upshot will not always be the "correct" judicial decision; but it will normally be a reasonable decision; and I would defend our Court's "right to die" decision on that basis. Our Court was adequately informed and prepared for that decision thanks mainly to an existing, and mature, public debate.

By way of contrast, let me mention two sets of issues, arising from developments in genetics, that may not yet have been subject to the kind of public discussion and debate that help to assure the soundness of a public policy decision. The first set arise out of genetic discoveries that permit doctors to forecast an increased likelihood that certain individuals will develop cancer. According to my scientifically-trained law clerk, the discovery of the BRCA1 gene in chromosome 17 means that certain women can learn they have what may be an 85% likelihood of incurring breast or ovarian cancer. Other genetic discoveries will identify other individuals with elevated cancer risks, say of a 10% or 20% likelihood they will incur the disease. The implications for public policy are widespread.

We are not truly used to the idea of knowing, in advance, who will and who will not develop a deadly disease like cancer. Where the risks are so great, accuracy is important; family information may be helpful; but relevant medical records are private. So there is a sense that some people should have a chance to get at private medical records. But on the other hand when the results of genetic testing can mean so much, people want, more than ever, to keep that information private. To what extent will modification of privacy policies prove desirable? And in which direction should protection of genetic privacy go? And who will provide for, and pay for, the psychological and family counseling that would often seem necessary? The diagnostic revolution may transform the existing public policy debate about environmental contributors to disease — contributors like diet or exposure to carcinogenic substances. Law has not, and could not, make our environment free of carcinogens. Instead, we tolerate the presence

of carcinogenic chemicals in numerous products that are useful to everyday modern life, such as gasoline, pesticides, or barbecued foods. We do so because the risks are relatively small, difficult to eliminate in their entirety, and we do not know in advance who will succumb to them. But what will happen if certain of those products create large risks for a few individuals whom we can identify in advance? How can we, how should we, selectively regulate their exposure?

Our greater ability to predict disease at the individual level poses especially difficult questions for legal regimes that rely upon our inability to do so. Our laws typically permit insurance rates to reflect comparative individual risks of death or disease. Often the man who has suffered three heart attacks already must pay more for insurance; nor does a new employer always have to hire him. Will the law continue to permit this kind of selectivity when genetic testing permits more accurate and long range predictions of disease risk? Should the law forbid some, or all, such discrimination? Does it make sense, as some states have already done, to create a new category of "genetic discrimination," and treat it like discrimination based upon race or gender?

For the law, these questions are difficult to answer, and not simply because they demand specialized inter-disciplinary knowledge. In addition, their answers depend upon social consequences that are not yet certain. We are a little like late-Victorians asked to predict the social consequences of the automobile. And the science itself, say in respect to cancer and its causes, continuously changes, which changes, in turn, pose new policy questions or demand new answers. We are asked to hit a moving target.

Nor surprisingly, policy change so far seems to have occurred primarily in those area of law where change itself is more easily revised or reversed— for example rules governing funding, professional responsibility, or ethics, and administrative regulations or Executive Orders, all of which embody a degree of necessary flexibility. The question for the future is whether these "oncology-related" problems are will require the kind of statutory change, or judicial interpretation of important statutes or even the Constitution, that carries with it a degree of legal permanence.

Let me turn to a second, more purely legal, area where rapid developments in genetic research has led to calls for legal change, namely patent law. If an inventor creates a product or process that is "useful," "novel," "non-obvious" and which does

not simply consist of "laws of nature, natural phenomena or abstract ideas," then the patent law, in return for disclosure, grants the inventor a twenty year monopoly over that product or process. This patent law approach is a one-size-fits-all approach. The question is, does it fit the world of genetic research?

The Supreme Court has held that that patent law does not distinguish between "living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *Diamond* v. *Chakrabarty*, 447 U. S. 303, 313 (1980). In principle, "anything under the sun that is made by man" can be patented — if it meets the four (and a few other) requirements. *Id.* at 309. But that is just the beginning.

We have seen scientists obtain patents for isolating, through hard work and considerable financial investment. a previously unknown sequence of DNA useful, say, in agriculture or medicine. An example is the BRCA1 gene discussed earlier, and its mutant forms. But what about granting patents on a mere gene fragment whose utility is only as a probe for finding the gene itself? What about patents for the isolation of cell membrane receptors?

The most difficult question is deciding when these or other products of genetic research reflect only discovery of an existing aspect of nature, like Einstein's discovery of the principles of relativity, and when they amount to a protectable invention or useful device. Should it matter if the more apt description of the scientist's work is the "discovery" of how a portion of the body functions, rather than the "invention" of how to use a part of that body to perform a useful, say, diagnostic, task? This latter question will sometimes seem unanswerable. Cloning a previously unknown DNA sequence is a little like the "discovery" of a preexisting part of the human body; it is also something like the expensive, time-consuming and novel isolation of previously unknown molecule.

It might be more helpful to ask instead how well patent law's sub-classifications and precedents here fit patent law's basic job. That job is developing financial incentives that, as they operate in the marketplace, will encourage useful discovery and disclosure without unduly restricting the dissemination of those discoveries, hindering the circulation of important scientific ideas, or scattering ownership to the point where it inhibits use of the underlying genetic advance. And — if patent law's legal

categories do not well match that law's basic objectives where genetic research is at issue — how should the law be changed?

This basic question leads to others. Do these problems reflect misapplication of the law's existing categories in lower courts? If so, could higher courts revise those decisions, say, with the help of guidance of the sort I have already described? Should Congress revise the patent statutes, revising categories or creating special forms of protection? How do we strike a proper balance between the resulting legal complexity and the simplicity promised by a "one size fits all" law of patents?

I raise these questions to point out that what might seem a more purely legal question nonetheless calls for the expertise, not only of lawyers, but also of economists, scientists, the biotechnology industry, and those familiar with the operation of the capital markets. The best answers will arise when the legal issue is focused by previous conversations between science, business, economics, and law. Neither courts nor legislatures may yet find wise answers in the absence of such earlier interaction.

Why have I contrasted the "right to die" case on the one hand with oncogenes and patent law on the other? Because through that contrast I hope to distinguish what is often a more helpful, from a less helpful, way for scientists, courts and legislatures to interact.

The less helpful, but traditional, model of interaction looks at the policy making process as if it consisted of powerful decision-makers limited to the choice of permitting or forbidding certain conduct. Interested parties, in this traditional lobbying model, submit information urging the decision maker to support or not to support, to ban or not to ban, a scientific development or activity based upon its potential for further benefit or harm. This model is clear. It sometimes works well. Remember Albert Einstein writing to Franklin Roosevelt about the need to develop atomic energy. But I do not believe that obtaining the ear of an elected official, even a President, is as critical as sometimes is believed.

The approach the traditional lobbying model suggests is not always helpful where genetic research is at issue. You may recall that in the early 1970's some individuals, including some highly informed scientists, believed that developments in genetic engineering entailed serious social risks. Following the traditional lobbying model, they presented their views to Congress; and they

asked for the enactment of moratoriums on, or prohibitions of certain genetic research. They did not succeed in obtaining legislation. And one can easily imagine the harmful consequences to which bans might have led. Genetic research so far has not led to the creation of the "mosquito-man" nor does cloning seem likely to produce multiple carbon copies of General Franco as once was feared. Rather that research has led to enormously beneficial discoveries related to our health and well being. That is not surprising. History suggests that government efforts to direct or control free thought and research impose major social costs. With hindsight, one might say that the effort to obtain legislation significantly limiting or banning research misplaced, both in respect to its timing and its approach.

My contrast suggests the virtues of a different model. In this model scientists, other experts, lawyers, legislators, perhaps judges too, engage in an on-going extended policy-oriented conversation — outside legislative or judicial forums. It is a conversation that takes place in writing or at conferences, in articles or at lectures, likely prior to, though perhaps contemporaneously with, direct consideration by courts or by legislatures of major statutory changes. It helps to inform the public debate that inevitably surrounds legislative change, in part by diminishing the likelihood the public will react to "outlier" examples, say mosquito-men or carbon copies of General Franco.

As an example, consider the seminar on the regulation of electricity, the Harvard Electric Policy Group, sponsored by Harvard's Kennedy School of Government and attended not only by professors of economics and government, but also by regulators, industry executives, representatives of consumer and environmental groups, lawyers, and even an occasional judge. The seminar provided and continues to provide a forum, not for negotiating, but for the discovery of common approaches to the facts, identification of the relevant unknowns, and the creation of areas of agreement and disagreement. This kind of development, I believe, has helped major change in public policy respecting electricity generation to proceed on a reasonably informed basis.

The conversational metaphor is not new. I want only to reaffirm its value as an aid to bringing about sensible legal reactions to scientific and technical change. It foresees a mature interaction between reasonable parties and an institutional relationship in which law neither ignores science nor reacts like a scold. It potentially includes, not just scientists or just scientists and policy makers, but all significantly affected groups within its

interactive scope. It suggests that judges or legislatures may wait to see what consequences, good or bad, actually result. It looks to readily revisable kinds of legal change when the need for immediate legal action is pressing. It recognizes the difficulty of predicting in advance what effects major scientific advances may have. And it aptly describes how law best develops in a democratic society — not imposed from on high, but bubbling up out of interactions among informed, interested groups and eventually with the public at large.

The courts cannot lead such conversations, though sometimes judges may participate. Rather courts are more likely ultimately to determine the statutory or constitutional "reasonableness" of solutions proposed by others. And the courts work best when they are well informed. Judges are at ease when they can rely upon what has come before.

Michael Oakeshott, in describing liberal education, better explained what I have in mind. "The pursuit of learning," he said, "is not a race in which the competitors jockey for the best place, it is not even an argument or a symposium; it is a conversation. . . . [E]ach study appear[s] as a voice whose tone is neither tyrannous nor plangent, but humble and conversable. . . . Its integration is not superimposed but springs from the quality of the voices which speak, and its value lies in the relics it leaves behind in the mind of those who participate. . . ."

But I need not tell you this. You are sponsoring such a conversation now. To you my basic point, is that a dialogue with the courts, judges and lawyers, depends for its success upon earlier, or ongoing conversations with many other groups as well. The task — that of creating a generalist voice that will speak for an age of specialization — is difficult to accomplish but it is important to try.

As I said at the outset, I am very pleased to have had an opportunity today to participate in that effort.