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Law and Ignorance:
Genetic Therapy and the Legal Process

Roger B. Dworkin*

Like most new developments in medicine and biotechnology, human gene therapy holds out the promise of substantial benefits to humanity while threatening both specific health hazards and fundamental damage to human dignity, and challenging us to consider the very limits of humanness. This combination of promise, threat, and challenge is what makes the subject interesting, not only because the advantages and disadvantages of gene therapy must be weighed and evaluated, but because the weighing and evaluating must take place in the face of overwhelming ignorance. That ignorance poses the most difficult kind of puzzle for persons who must consider what the social response to human gene therapy should be.

In some sense, of course, social policy makers, law makers, always act in the face of ignorance. No matter how conscientiously lawmakers may have studied a problem, no one can foresee the full range of consequences that will follow from legal enactments or decisions. Ignorance, however, is a matter of degree. In most situations ignorance is a minor factor in the legal equation. Lawmakers usually know, or at least think they know, a great deal about the area under consideration. In considering gene therapy, however, ignorance is the essence of the legal dilemma. The question is whether and how to regulate in an area that is ill understood and whose ramifications can only be imagined. Regulating in the face of overwhelming ignorance presents the law with a terrible dilemma—balancing the imperative of protecting society from unknown, but imaginable evils with the imperative of refraining from adopting law that will be unwise, freeze the growth of

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4 Jahrbuch für Recht und Ethik, Bd. 4 (1996)
science and technology, and deprive society of unknown, but imaginable benefits. How to resolve that dilemma is the subject of this paper.

**Gene Therapy**

Broadly speaking, gene therapy may be classified either as somatic cell therapy or as germ-line therapy. Somatic cell therapy involves an effort "to treat an individual patient, e.g., by inserting a properly functioning gene into a patient's somatic [nonreproductive] cells."¹ Germ-line therapy, on the other hand, involves an effort "to introduce genetic changes into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring."²

Further classification that takes into account the purpose of the therapies is possible. Thus, one can subdivide both somatic cell and germ-line therapy into therapies intended to cure or prevent disease and those intended to enhance the characteristics of healthy persons.³

Despite the fact that successful somatic cell therapy will increase the number of homozygotes who will pass disease genes to their offspring⁴ and some public uneasiness about such therapy,⁵ a broad consensus exists that somatic cell therapy to correct serious diseases of identifiable human beings is ethically acceptable.⁶ No such consensus exists about the acceptability of germ-line therapy,⁷ and most government, professional, and religious groups that have taken a position on germ-line therapy oppose its use.⁸ The few groups that have taken a position on the use of gene therapy for enhancement, rather than to cure or prevent disease, oppose that use of genetic technology.⁹ Indeed, concern that germ-line therapy will be used to

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² Id.
⁷ Id.
⁸ Id.
⁹ Id.; see Alex Mauron/Jean-Marie Thévoz, "Germ-Line Engineering: A Few European Voices", 16 J. Med. & Phil. 649, 651 (1991), noting that a large consensus exists against the use of germ-line engineering to "improve" human beings.
pursue genetic enhancement is one reason that some critics oppose germ-line therapy.

Several different arguments are made against germ-line therapy. Eric Juengst has suggested that five basic arguments exist: (1) arguments based on scientific uncertainty and clinical risks; (2) "slippery slope" arguments based on the fear that germ-line therapy to fight disease will inevitably lead to its use for enhancement; (3) arguments based on the impossibility of obtaining the consent of future generations; (4) arguments based on the view that resources devoted to developing germ-line therapy could be better spent elsewhere; and (5) arguments based on the importance of maintaining the genetic patrimony.10

The resource allocation argument is neither very interesting, nor very important. One can always argue about whether it would be "better" to devote resources to feeding the hungry, preventive medicine, or research that is likely to help a large number of people than to developing an entirely new, problematic approach to confronting disease. Nothing about germ-line therapy makes that argument any different here than it would be in the case of somatic cell therapy or therapies that do not involve genetic technologies.

Similarly, arguments based on scientific uncertainty and clinical risk usually attend efforts to develop new approaches to fighting disease. Well established ethical codes and legal procedures exist to govern the development of new drugs and medical devices. Elaborate procedures for the protection of human subjects are in place. To the extent that developing germ-line therapy involves experimentation with identifiable human subjects and efforts to develop new "drugs", existing procedures are no less adequate than they are in the context of developing other kinds of new therapeutic agents.11

Nonetheless, even the resource allocation and scientific uncertainty-clinical risk arguments are rooted in uncertainty. We do not know what the payoff for germ-line research will be or how its benefits will compare with those that could be achieved through different resource allocations. And, by definition, arguments about scientific uncertainty are arguments about what to do when we do not know what the outcome of different courses of action will be.


The other arguments against germ-line therapy require more attention. One major concern is that the use of germ-line therapy to cure disease will lead inevitably to its use for enhancement, that is, that germ-line therapy will become a tool of positive eugenics.\textsuperscript{12} This argument assumes (1) that enhancement, or at least enhancement that is not a form of preventive medicine,\textsuperscript{13} is so inappropriate that it ought not to be permitted regardless of what legitimate benefits are lost through the prohibition, and (2) that persons and society will be unable or unwilling to draw a line between medical and enhancement uses of germ-line therapy. Since the line cannot be drawn, all uses of germ-line therapy must be prohibited.

Neither of these assumptions is susceptible to proof. Perhaps what seems an enhancement today will turn out to be a disadvantage; perhaps humans lack the wisdom to make wise choices about which traits to promote and at what rate; perhaps any change in the natural order of trait distribution will constitute an evil. But perhaps the opposite will turn out to be true. As Burke Zimmerman has argued, "There are no inherent objections to carrying out genetic 'enhancement' in individual cases . . .". We must simply be especially careful in evaluating the criteria for deciding which enhancements are appropriate.\textsuperscript{14} Will enhancement lead to the dehumanization of future generations as people come to see themselves as artifacts? Will enhancement lead to injustice in the distribution of opportunities for enhancement and the benefits that will flow from it? Or is Resnik correct in suggesting that these harms are either unrealistic or avoidable?\textsuperscript{15} One can have an opinion, but one cannot know.

Similarly, the argument that it will be impossible to draw lines is an assertion that may or may not turn out to be correct. Somatic cell therapy is sometimes used for enhancement, as, for example, when genetically engineered human growth hormone is administered to short children who have no pathology in an effort to make them taller. Does that use of enhancement therapy prove that we cannot draw lines so that somatic cell therapy should not have been allowed? Or does the standard argument that treats somatic cell therapy and germ-line therapy as significantly different demonstrate that lines can be drawn? Berger and Gert argue that it is possible to define a "malady" and to limit germ-line therapy to the correction of maladies.\textsuperscript{16} Yet their distrust of human beings makes them unwilling to rely on people doing that and leads them to counsel against the use of germ-line therapy lest a

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\textsuperscript{14} Zimmerman, supra fn. 4, at 610.

\textsuperscript{15} Resnik, supra fn. 12.

\textsuperscript{16} Berger/Gert, supra fn. 12, at 671.
few people benefit at the expense of many. Which view is correct, the one based on the logical possibility of defining maladies, or the one based on a negative view of human nature? Nobody knows.

Thus, both halves of the slippery slope argument are based on unproved assumptions. The lawmaker who acts out of concern for the dangers of the slippery slope will be acting on the basis of unfounded predictions, not on the basis of information.

A lack of information also bedevils the claim that we should not engage in germ-line therapy because we cannot obtain the consent of the next generation. By definition, successful germ-line therapy will affect persons yet unborn. They are unable to decide whether to consent to the risks of germ-line therapy or its proposed benefits. Therefore, the argument goes, we should refrain from using germ-line therapy.

On one level this argument is strikingly unpersuasive. Children cannot consent to any kind of therapy; their parents or guardians consent for them. Almost everything that a pregnant woman does may have an impact on her unborn child. That fact does not disable the woman from existing, and most maternal behavior is tolerated even if some other course of conduct would clearly be better for the fetus. Even some experiments are allowed to be conducted on children. Thus, in other medical contexts the inability of a patient or subject to consent does not require us to refrain from action. Why should it do so here?

Part of the problem of the inability of future generations to consent is based on factual ignorance. We do not know whether an unborn or unconceived person would consent to a particular procedure. But often in medicine we do not know what an incompetent person would consent to. In all other situations we solve this problem by assigning a surrogate decision-maker and adopting a substantive standard, typically either substituted judgment or the best interests of the patient, for the decision-maker to apply. Thus, ignorance about incompetent persons' preferences does not block action elsewhere, and, by itself, it seems insufficient to block it here.

17 Id, at 680.
18 See generally Roger B. Dworkin, "Common Sense and Common Decency: Some Thoughts about Maternal-Fetal Conflict", 1991 Biomedical Ethics Reviews 9 (J. Humber/R. Almeder, eds.).
20 This approach has been developed most fully in litigation about the so-called right to die. See generally, e.g., Cruzan v. Director, Missouri Department of Health, 110 S. Ct. 2841 (1990); Superintendent of Belchertown State School v. Saikewicz, 370 N.E.2d 417 (Mass. 1977); In re Quinlan, 355 A.2d 647 (N.J.), cert. den. sub nom. Garger v. New Jersey, 429 U.S. 922 (1976).
Nonetheless, riding roughshod over persons who cannot consent is very worrisome, and the inability of a person to consent to a procedure that affects him or her should certainly give us pause. The problem here, however, is that we do not know whether there is any "person" or other entity deserving of moral consideration involved. Some forms of germ-line therapy involve manipulation of embryos, beings whose moral status is unclear and controversial. Other forms, however, would involve alterations to the cells of living persons with the purpose of affecting those persons' future, as yet unconceived offspring. What does it mean to talk about the consent or non-consent of an unconceived person, especially if the consequence of refusing to do germ-line therapy is that the person will never be born? The unconceived are not thought to have a right to consent to other decisions affecting their genetic makeup — whether their father or mother marries a blond or a brunette, an athlete or a scholar, a carrier of the gene for Huntington's disease or a non-carrier. What is the case for recognizing an entitlement to consent in the one instance of germ-line therapy, an instance in which the entire point of the intervention is to permit the unconceived person to be born and to be healthy?

Perhaps the point is one that transcends the individual. Perhaps there is an obligation to maintain the genetic patrimony. Mauron and Thévoz describe the idea that there is a basic human right to one's unmodified genetic endowment, or "genetic patrimony". This right is a collective one; there is a "collective genetic heritage" that is worth more than any individual interest. "[O]ne cannot touch the 'genetic patrimony' even if some persons would benefit."

Why not? The "genetic patrimony" of all species has changed naturally over time. Only a mystic commitment to the natural would suggest that humanly caused alterations are somehow less acceptable than natural ones. Surely, the notion that natural is best is out of keeping with all developments in modern medicine and cannot be taken seriously. The argument, then, must be that in the area of germ-line therapy our unnatural interventions will take us down a path we cannot know, and that an unknown path is one we should not tread. This is, of course, the argument based on ignorance once again. Ignorance plus pessimism leads to the conclusion that germ-line gene therapy should not proceed.

The arguments in favor of germ-line therapy are hardly more convincing. Here too Eric Juengst suggests that there are five basic arguments: (1) medical utility,

\[\text{Mauron/Thévoz, supra fn. 9, at 654.}\]

\[\text{Dorothy C. Wertz, "Leave the Door Open to Research", 13 Politics & the Life Sciences 235 (1994). "It is not clear why hazards of nature should necessarily be better than achievements of science. . . This view overlooks the importance of artificial components in our lives and activities. We are artificial beings by our very nature. The human intelligence and consequent capability of innovation and creativity also belong to nature." Group of Advisors on Ethical Implications of Biotechnology of the European Commission, Report on Ethical Aspects of Gene Therapy 13 (1994) (Archer Report), quoted in: Note (Charles F. Delager), "The Development of Regulatory Standards for Gene Therapy in the European Union", 18 Fordham Internat'l L.J. 1303, 1334 (1995).}\]
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(2) medical necessity, (3) prophylactic efficiency, (4) respect for parental autonomy, and (5) scientific freedom.23

The first three arguments are all based on predictions about germ-line therapy—that it will be useful for curing disease, that it may be the only way to cure some diseases, and that it will prove cheaper and safer in the long run than frequent use of somatic therapy. Maybe these predictions will turn out to be correct, but we do not know whether they will. Germ-line therapy is still remote. How useful, necessary, and efficient it will turn out to be if we allow it to develop remains to be seen.

The last two arguments, like opponents' arguments about unconsenting future generations and the genetic patrimony, are simply assertions that one may or may not accept. Parental reproductive autonomy is hardly unquestioned in the world today. Even one who accepts the idea in the abstract may well think there is a difference between prohibiting the police from regulating activities in the marital bedroom and promoting research and therapy that will allow a parent to control the genetic makeup of his or her child. Indeed, the claim of parental autonomy is the argument that leads most obviously to the suggestion that germ-line therapy will be used for enhancement and that, therefore, it should not be permitted.

Similarly, everyone now concedes that scientific freedom has limits. Some research is simply too awful to do, and many restraints are imposed on research with human subjects and with animals. Whether the research necessary to develop germ-line therapy is such research is a question. Its answer cannot simply be assumed.

Thus, the arguments for and against germ-line therapy all rest on unprovable factual suppositions or arguable assertions of values. How ought a lawmaker to respond when confronted with such arguments?

Process Values

The most obvious and tempting response, of course, is simply to choose one set of arguments to believe and adopt the policy that will promote one's point of view. A scientific optimist or adherent of parental or scientists' rights will support germ-line therapy and oppose its legal prohibition; a pessimist or advocate for the autonomy rights of the unborn or the communal genetic patrimony will oppose the therapy and seek to have it banned. Indeed, an extreme adherent of this view will oppose all technological developments that pose even the slightest risk of catastrophic consequences.24

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23 Juengst, supra fn. 10, at 589-90. See also Rubenstein/Thomasma/Schon/Zinaman, supra fn. 10, at 329-332.

24 See, e.g., Mauron/Thévoz, supra fn. 9, at 659, discussing the work of Hans Jonas.
What these supportive and antagonistic positions about gene therapy have in common is that they are based exclusively on substantive considerations—the desirability or undesirability of germ-line therapy. What they both forget is that all law also involves another set of values, the values that underlie the legal system. A legal system has its own ends to serve and its own institutions for serving them. Law made without devoting attention to these process values will inevitably be unsuccessful from everybody's point of view, including the point of view of those who appeared to succeed in having the law adopt their position.25

Careful attention to process and to the characteristics of legal institutions suggests the lack of wisdom in adopting extreme legal positions in the face of uncertainty. Law is a collection of tools of limited utility, which can make only limited contributions to the resolution of social issues posed by rapidly developing medical technology.

This is not surprising. All legal institutions are created and operated by human beings whose scientific knowledge, ability to predict the future, and wisdom about matters of ultimate moral significance are all extremely limited. Moreover, the institutions these human beings have created are not designed to choose between arguable positions in which much that is desirable inheres on both sides of the issue. The law can choose between right and wrong, but in the area of germ-line therapy, as in most of bioethics, there is right on all sides of the issue. The choice is not between right and wrong, but rather between ways to sacrifice the least that is right, or good, in all positions. As Paul Freund noted years ago, "The law is dialectic in a deeper sense than its adversary process. It mediates most significantly between right and right".26

If the goal of the law is to mediate between right and right, then it makes little sense to think that the law should adopt an extreme position about germ-line therapy. Either prohibition or unfettered development will sacrifice all that is "right" about the other point of view. Thus, legislation or, at least in the United States, worse yet, constitutional adjudication that prohibits germ-line therapy or estab-

25 The great seminal work in establishing the overriding value of process to law is Henry M. Hart, Jr./Albert M. Sack, The Legal Process, which after circulating in mimeographed form for decades, is finally available in a hard cover, printed edition. (William N. Eskridge, Jr. and Philip P. Frickey, eds., 1994). For an effort to apply legal process analysis to the field of bioethics in general see, Roger B. Dworkin, Limits: The Role of the Law in Bioethical Decision Making, (forthcoming), which, among other things, explores at great length the Pyrrhic victory won by American abortion rights advocates who let their substantive goals blind them to the dictates of procedural good sense.

Andrea Bonnicksen, who does not specifically mention process or process values, offers an interesting argument that national approaches to germ-line therapy are preferable to international ones for reasons that are rooted in considerations of legal process at the national and international levels. Andrea Bonnicksen, "National and International Approaches to Human Germ-Line Gene Therapy", 13 Politics & the Life Sciences 39 (1994).

lishes rights to pursue the therapy as a form of parental autonomy or scientific freedom would be a serious mistake.

In order to mediate between right and right, the law should adopt the least intrusive institutional approach that can achieve the balance that is needed to avoid losing too much that is valued by persons on all sides of the issue. In this context what that suggests is the adoption of administrative regulations that will permit germ-line therapy to be developed and used subject to relatively easily changed controls to prevent abuse and reduce the risk of injury.

Common law case development, which in the common law world is generally the least intrusive form of law, will not suffice here. One of the primary goals in regulating germ-line therapy is to control the conduct of researchers and physicians. Common law adjudication, which operates after-the-fact, resolves cases one at a time, and is highly fact-specific, lacks the clarity, generalizability, certainty, and predictability to be effective at conduct control.

Conversely, legislation, and especially criminal legislation, which is more effective than common law at controlling conduct, is both too political and too extreme to deal well with an area like germ-line therapy. Legislators are unlikely to be scientifically sophisticated; they make decisions that are partly based on political (i.e., irrelevant) considerations; their enactments are difficult to adopt and, therefore, difficult to change if they turn out to be ill-advised or if they become outdated; and the limitations of language and the abstract nature of their pronouncements make it difficult for them either to paint with a fine brush or to achieve the certainty that legislation seems to offer. Criminal legislation shares all these problems, but in criminal law they are exacerbated by the extreme, morally ambiguous venture on which the law has embarked — the intentional infliction of pain by the state. Only conduct that is almost universally condemned as immoral should be subjected to criminal penalties, and, even then, subject to numerous prudential constraints. Obviously, germ-line therapy, which offers potential for great human benefit, does not qualify.

If legislation is an inappropriate response to germ-line therapy, then constitutional adjudication, the legal system's most extreme response, is even more so. Constitutional adjudication establishes principled, national, sweeping rules that are unlikely to be sound in areas that have little to do with the nature and structure of government, and that are characterized by intense moral conflict, rapidly changing facts, and scientific information which judges are ill-equipped to understand.

Administrative agencies are the legal institutions best suited to consider the issues presented by germ-line therapy. First, agencies are staffed in part by persons with expertise in the fields being regulated. Therefore, they are more likely than inexpert judges or legislators to be able to understand the technical aspects of the

issues before them. Second, agencies are able to adopt regulations, which give them greater ability to control conduct than common law courts. Third, they also have the ability to decide specific cases, thereby giving them more ability to draw subtle factual distinctions than legislature. Fourth, they are staffed in part by civil servants who are better insulated from politics than legislators. To the extent that the civil servants are subject to political influence, at least it is political influence relevant to the broad mandate of their agency. That is, unlike a legislator, an employee of the Food and Drug Administration cannot be pressured to trade a vote about germ-line therapy for a vote on the location of a new military base.

Of course, the time for an idealistic, romanticized vision of administrative agencies is long past. Everybody understands that agency proceedings can become bureaucratic nightmares and that industry groups can capture control of the very agencies that are supposed to be regulating them. The argument here is not that administrative agencies are ideally suited to deal with germ-line therapy, only that they are better suited than any other legal institutions. Surely agencies are more able than other institutions to make incremental, tentative, experimental steps in regulating germ-line therapy and to change their approach if it seems on reflection to be wrong or if scientific changes suggest the need for policy changes.

Thus, if one focuses on process rather than substance, one comes to the conclusion that there should be no legislation about germ-line therapy, other than to assign authority to an administrative agency; that the agency should permit some development of germ-line therapy, subject to careful restrictions; and that as the scientific, social, and moral status of germ-line therapy becomes clearer, the agency should reconsider its position regularly and often.

**Process versus Substance**

Focus on substance suggests to many people that germ-line therapy should be prohibited, and may suggest to a few that it should be permitted without restriction. Focus on process suggests that both of those positions should be rejected and that minimal legal involvement should be used to allow the technology to develop slowly while retaining the power to stop it if that becomes desirable. The question, then, becomes how is one to choose between substantive values and process values in deciding what to do about germ-line therapy?

This may be the place at which ethics and law diverge. An ethical analysis may lead to a firm conclusion that one course of action is better than another. A person who comes to such a conclusion is likely to believe that this "correct" position should be adopted and imposed. Thus many ethicists have concluded that germ-line therapy ought not to be permitted.28

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A lawyer, on the other hand, is likely to be doubly skeptical. The lawyer will be reluctant to believe that the ethical analysis has really reached the right answer; indeed, the lawyer is likely to doubt the ability of human beings to ascertain right answers to any questions worth asking. Thus, the lawyer will be reluctant to enshrine one viewpoint in the law. Second, the lawyer will be skeptical about the ability of the law itself.\textsuperscript{29} Nobody understands the limitations of a set of institutions and procedures as well as those who work with them every day.

Regardless of whether professional orientation predisposes to one course of action or another, something must be said about the relative importance of substance and process in the area of germ-line therapy. Substantive positions on the issue are, as we have seen, rooted in ignorance and bald assertion of preferences. This makes them a slender reed on which to rest public policy. Moreover, adopting a position based on the substantive arguments will have catastrophic results if the decision turns out to be wrong. Permitting unfettered development and application of germ-line therapy may lead to injury to living persons and to generations yet unborn. It may lead to dehumanization, to undesirable uses of genetic enhancement, and to the exacerbation of social inequity. It may lead to serious damage to our collective genetic essence. All of those consequences obviously should be avoided. On the other hand, prohibiting germ-line therapy will almost surely deprive medicine of an important tool in the fight against disease, squander an opportunity to eliminate some serious diseases altogether, leave many patients with the Hobson's choice of refraining from reproduction or deciding to propagate or risk propagating children with serious genetic disorders, and cost society large sums of money to treat avoidable conditions. Those, too, are obviously consequences to eschew.

Following the dictates of process, on the other hand, minimizes the costs of mistakes. Adopting the administrative approach suggested above will provide some of the benefits of germ-line therapy with only minimal risk and will permit receipt of expanded benefits if the risks do not materialize. It will not commit society to one course or another. It will act upon the recognition that the best course of action in the face of ignorance is to temporize until the ignorance is overcome. Thus, in the instance of germ-line therapy process values seem clearly to point toward a sounder direction for social action than substantive values do. This is one of the many areas in which how one proceeds is the surest guide to what one ought to do.

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\textsuperscript{29} See, e.g., the views of Cecil Clothier, Chair of the British Committee on Gene Therapy, who called the law "a fairly blunt instrument," and stated, "As a lawyer, I would depurate any sort of legal control [on gene therapy] at this stage, because we do not know what we are controlling." \textit{Phylilda Brown}, "Gene Therapy Wins Official Blessing", 133 New Scientist 18 (Jan. 25, 1992).
Actual Legal Response

To the extent that various nations and international groups have dealt with germ-line therapy to date, their record is mixed in terms of pursuing what I have suggested is the best approach. A few examples will illustrate the point.

Germany has made it a crime to artificially alter “the genetic information of a human germ line gene” or to use “a human germ line gene with artificially altered genetic information”. This approach seems to be an overuse of the criminal sanction and to fail to take advantage of the benefits that greater attention to process values could provide.

The United States has taken a somewhat more moderate position, but still one that effectively precludes germ-line therapy. Gene therapy at institutions that receive any National Institutes of Health (NIH) support for recombinant DNA activities is governed by NIH guidelines. In addition, the NIH and the Food and Drug Administration (FDA) collaborate to control research directed at the production of new drugs and other biological products. Gene therapy is regulated according to Appendix M. of the guidelines, the so-called “Points to Consider”. Under the Guidelines gene therapy may not be performed unless the NIH’s Recombinant DNA Advisory Committee (RAC) has approved the protocol. The Points to Consider state, “The RAC will not at present entertain proposals for germ-line alterations but will consider for approval protocols involving somatic cell gene transfer”. Thus, the current position in the United States is clear. No germ-line therapy may be performed except by somebody at an institution that neither receives NIH support for recombinant DNA activities, nor intends to seek approval for their approach from the FDA. Effectively, this means that germ-line therapy is not permitted in the United States today.

In terms of the process oriented approach I have suggested, the American approach has some benefits. It remits decision making to an administrative agency with considerable scientific, legal, and ethical expertise. The agency recognizes the value of flexibility by stating plainly that its disapproval of germ-line therapy is its position “at present”, leaving open the possibility of changing its position should conditions warrant. On the other hand, NIH’s blanket rejection of germ-line therapy squanders the RAC’s opportunity to paint with a fine brush and exalts

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30 Bundesgesetzbblatt, Teil 1, 2746, 2747, Embryonenschutzgesetz § 5 (trans. by Ralph Gaebler).
31 Supra fn. 1, § I-C-1.
32 See, testimony of Dr. Nelson Wivel, supra fn. 11, at 22-23.
34 Id., at 34529.
35 Bonnicksen, supra fn. 25, at 43.
the substantive values of those who oppose germ-line therapy over the values of those who support it. Thus, the American position is more rigid than it needs to be, and it impedes possibly useful scientific development more than is necessary to achieve adequate protection from the feared evils of germ-line therapy.

Spain has two relevant statutes, one on the donation and use of human embryos and fetuses, and one on assisted reproduction procedures. The former permits genetic technology to be authorized,

For therapeutic purposes, principally for sex selection in the event of diseases linked to the sex chromosomes, particularly chromosome X, thereby avoiding their transmission; or to create beneficial genetic mosaics through surgery, by transplanting cells, tissues, and organs from embryos and fetuses into patients in which these are biologically and genetically modified or lacking.\(^{36}\)

The assisted reproduction procedures statute permits intervention on a human pre-embryo only to treat the pre-embryo’s disease or to prevent its transmission.\(^{37}\) The statute then establishes conditions for engaging in therapeutics with pre-embryos \textit{in vitro} or on pre-embryos, embryos, or fetuses within the uterus. One condition is,

That there is no influence on non-pathological hereditary traits, and no selection of individuals or of race is sought;\(^{38}\)

If these provisions stood alone, they could be read as leaving open the door to germ-line therapy. The first statute authorizes somatic cell therapy, but it is possible to interpret the language about creating beneficial genetic mosaics for patients in whom their cells, tissues, or organs are “genetically modified or lacking” to permit some germ-line therapy as well. Moreover, the emphasis in the assisted reproduction statute on preventing the transmission of disease, and the prohibition against influencing \textit{non-pathological} hereditary characteristics seems to imply that efforts to influence \textit{pathological} hereditary characteristics are permissible. This interpretation would mean that germ-line therapy, but not enhancement, would be permitted in Spain.

However, other statutory provisions make this interpretation unlikely.\(^{39}\) Article 14(3) of the assisted reproductive procedures law prohibits developing pre-em-


\(^{38}\) Id, Art. 13 § 3d.

\(^{39}\) I am indebted to Professor Gonzalo Herranz of the Universidad de Navarra for the following understanding of Spanish law.
bryos for procreation using gametes that have been used for experimentation.\textsuperscript{40} Article 20(2)(B)(i) declares transferring gametes or pre-embryos to the uterus without necessary biological or viability assurances to be a "very serious offense".\textsuperscript{41} As there is no practical way to obtain the necessary assurances, this means that the transfers cannot be made. Finally, the statute forecloses the use of human gene therapy on embryos conceived through sexual intercourse by making it a "very serious offense" to obtain "human pre-embryos by uterine lavage for any purpose;"\textsuperscript{42} and by prohibiting experimentation on pre-embryos in the uterus or fallopian tubes.\textsuperscript{43} Thus, as a practical matter, Spanish law seems to be as restrictive as German law and perhaps more restrictive than the American.

Israel deals with gene therapy through its control of research with human subjects. Any new procedure designed to affect the health, "including the genetic structure," of a person or fetus must be approved as a medical experiment on a human being.\textsuperscript{44} Any "experiment concerning the genetic structure of a person" cannot be approved unless the administrator has received a written opinion from a higher committee.\textsuperscript{45} This approach leaves open the question of whether the higher committee will ever approve a germ-line experiment and appears to give the administrative agency power to approve such an experiment if it thinks that doing so would be wise.

At the inter-state level, the European Parliament has expressed its disapproval of germ-line therapy.\textsuperscript{46} Nonetheless, the European Union has not yet adopted Union-wide gene therapy regulation,\textsuperscript{47} and the Archer Report evaluating gene therapy, which was prepared at the request of the Commission, took the position that the great promise of germ-line therapy makes such therapy a "medical imperative".\textsuperscript{48}

The Council of Europe has had considerable difficulty in deciding on a position regarding germ-line therapy. In 1982 the Parliamentary Assembly took the position that the rights to life and human dignity "imply the right to inherit a genetic pattern which has not been artificially changed".\textsuperscript{49} Nonetheless, the Assembly recognized the importance of not impeding the development of gene therapy\textsuperscript{50} and re-

\textsuperscript{40} Act on Assisted Reproduction Procedures, supra fn. 37, Art. 14 § 3.
\textsuperscript{41} Id, Art. 20 § 2 B i.
\textsuperscript{42} Id, Art. 20 § 2 B b.
\textsuperscript{43} Id, Art. 16 § 4.
\textsuperscript{44} The Laws of Israel, Chapter 12, Health, § 1.4 (1) (trans. by Derek Penslar).
\textsuperscript{45} Id, § 1.4(3)(b).
\textsuperscript{47} DeJager, supra fn. 22, at 1314.
\textsuperscript{48} Archer report, supra fn. 22 at 11, quoted in: DeJager, supra fn. 22, at 1333, n. 249.
\textsuperscript{49} Council of Europe, Parliamentary Assembly Recommendation 934 (1982) on genetic engineering ¶ 4i.
\textsuperscript{50} Id, ¶ 4.iii.
commended that the Committee of Ministers recognize the right to a genetic inheritance that has not been interfered with “except in accordance with certain principles which are recognized as being fully compatible with respect for human rights (as, for example, in the field of therapeutic applications)”. In 1986, the Parliamentary Assembly interpreted its 1982 position as recognizing “the right to a genetic inheritance which should not be artificially interfered with except for therapeutic purposes”. Explicit recognition of an exception for therapeutic purposes seemed to be a rejection of absolutism and to leave open the door to germ-line therapy. However, in 1989 the Parliamentary Assembly stated clearly, “Any form of therapy on the human germinal line shall be forbidden”.

Most recently, the Council of Europe has prepared a draft bioethics convention. That convention, if adopted, would authorize somatic cell gene therapy related to disease. It would, however, prohibit somatic cell enhancement therapy and all germ-line therapy. The drafters concluded that current scientific uncertainty about the effects of germ-line therapy on future generations and concern about imperilling the human species itself required them to ban germ-line therapy.

Thus, the present international situation with regard to genetic therapy is in flux. Somatic cell therapy for the treatment of disease seems to be widely accepted, although methods of regulating such therapy differ from country to country. Germ-line therapy is usually rejected. However, no ethical consensus opposed to germ-line therapy exists, and most countries have refrained from enacting a definitive ban on such therapy. A consensus that rejects enhancement therapy does seem to exist. A persuasive demonstration of the possibility of drawing a workable line between pathological and non-pathological conditions would probably go a long way toward removing opposition to germ-line therapy by removing the fear of the slippery slope to genetic enhancement.

51 Id, ¶ 7b.
52 Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986), Use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes ¶ 1.
53 Council of Europe, Parliamentary Assembly, Recommendation 1100 ¶ 18 (1989), supra fn. 36.
55 Id, Art. 16 ¶¶ 109-112.
56 Id, Art. 16 ¶ 112.
57 Id, ¶¶ 10-11.
People and nations respond to uncertainty in different ways. As we have seen, the Council of Europe’s response to scientific uncertainty about the risks of germ-line therapy is to suggest banning the therapy.\(^{58}\) Germany has done so.\(^{59}\) This is consistent with the view that a technology must be rejected if it presents even the slightest possibility of a catastrophic consequence.\(^{60}\) Other prohibitionist views can be traced to modesty about human abilities. Mauron and Thévoz have stated that germ-line therapy means curing tomorrow’s people with today’s techniques and conceptual tools. They argue that germ-line therapy should be rejected because it may give excessive, lasting power to a contingent state of medical science.\(^{61}\) Similarly, Berger and Gert argue that unless we have almost certain knowledge about the risks of germ-line therapy, no benefit to a small number of people can outweigh the risk to many.\(^{62}\)

Conversely, some people respond to uncertainty by emphasizing the possibility of benefits rather than harms. In its extreme form this view leads to the assertion that not only is germ-line therapy ethically acceptable, but that medicine has a moral obligation to pursue it.\(^{63}\)

This article has argued that prudence dictates rejecting the arguments of both the genetic optimists and the pessimists, and that sound policy lies in attempting to reap the potential benefits of germ-line therapy while avoiding its dangers. It has suggested that elevating the values of process over substance is the best way to achieve this balanced middle view.

Attention to process suggests that administrative regulation, rooted in expertise and committed to flexibility, is the most desirable way to respond to issues posed by the consideration of germ-line therapy. Adopting this approach would lead to reconsideration of the prohibition of germ-line therapy in countries like Germany and Spain, to rejection of the prohibition of germ-line therapy in the Council of Europe’s proposed bioethics convention,\(^{64}\) and to loosening of administrative prohibitions of germ-line therapy in countries like the United States.

\(^{58}\) See fn. 56, supra, and accompanying text.
\(^{59}\) See fn. 30, supra, and accompanying text.
\(^{60}\) See fn. 24, supra, and accompanying text.
\(^{61}\) Mauron/Thévoz, supra fn. 9, at 661-62.
\(^{62}\) Berger/Gert, supra fn. 12, at 680.
\(^{64}\) Indeed, attention to process may suggest the wisdom of avoiding all multinational approaches to the regulation of germ-line therapy, at least for the present. Bonnicksen, supra fn. 25, at 46-47.
Modesty about our ability to understand science is a desirable attitude. So too is modesty about the ability of legal institutions to make positive contributions to the control of science. Regulation rooted in that modesty is likely to prove the soundest course.65

Zusammenfassung


Soweit nationale Regierungen und internationale Körperschaften sich mit Fragen der Gentherapie befaßt haben, haben sie im allgemeinen nur unzureichend auf Verfahrenswerte geachtet und auf Bedenken gegenüber der Keimbahntherapie mit einem Verbot derselben überreagiert.

65 "Those entering this debate should recognize that their work is primarily in the realm of ideology, a treacherous territory. It is surely a realm where the full force of law should be left out, because of the lingering uncertainties, and where those engaged in the debate should proceed with due humility." Cook-Deegan, supra fn. 27, at 219.

5 Jahrbuch für Recht und Ethik, Bd. 4 (1996)