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TOWARD AN INTERNATIONAL STANDARD OF SCIENTIFIC INQUIRY‡

George P. Smith, II††

I. HUMAN RIGHTS AND THE NEW BIOTECHNOLOGY

UNTIL QUITE RECENTLY, the pervasive attitude among sophisticated observers in Australia, Europe and America has been one of support for scientific inquiry and discovery. It was believed that this progressive action was not only of overwhelming benefit to society, but an essential attribute of human achievement and progress in the brave new world.¹ Subsequent agonizing reflections on the horrors of the World Wars and the all too frequent limited conflicts since 1945, together sometimes with overly emotional concerns regarding the full potential for nuclear, bacteriological and chemical warfare and its very real potential for annihilating mankind, have witnessed a new and increasingly pessimistic temperament concerning scientific advancement. Indeed, it has been recognized that “not all science is good for humanity.”²

The importance of human rights and its need to be recognized in the era of the “New Biology” was underscored by initial efforts at the United Nations in the 1970’s.¹ But before that activity, the 1948 Universal Declaration of Human Rights guarantees of “human dig-
nity" written in Articles 1, 5, 6 and 29(1)\(^4\) established eloquent reminders of the need for the advances of biotechnology and genetic engineering to be tied to a basic understanding of, and respect for, fundamental human rights.\(^5\)

A new human rights debate needs to emerge among not only the legal community, but also among the scientists and technocrats; a debate that would reconsider the extent to which both the traditional and the re-defined rights of humanity are challenged or complemented by the plethora of medical, legal, scientific and technological considerations of today's brave new world. Mr. Justice Michael D. Kirby of Australia succinctly summarized the issue: "If lawyers are to continue to play a relevant part in the human rights debate of the future, they must become more aware of scientific and technological advances. Otherwise, they will increasingly lack understanding of the questions to be asked, let alone the answers to be given."\(^6\)

Law needs to direct an agenda for social change and changing social needs rather than simply responding or reacting to change. Indeed, former Chief Justice Warren E. Burger has observed, "The law does not search out as do science and medicine; it reacts to social needs and demands."\(^7\) Law, science and medicine must become partners. They must assure society today and tomorrow, that all citizens have an equal opportunity to achieve their maximum potential within the economic marketplace, have their physical suf-

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\(^5\) Kirby, supra note 1, at 179. Mr. Justice Kirby has cautioned that the increasing knowledge of human fertility and its varied and mechanical applications draw new attention to other human rights guarantees.

[Specifically] [c]an Art. 16(1) of the Universal Declaration, with its guarantee that men and women of full age have a right to marry and 'to found a family' provide support for a claim to \textit{in vitro} fertilization, embryo transplantation, artificial insemination, surrogate parenting and womb leasing, transplantation and the like? Is the guarantee of special care and assistance for motherhood and childhood in Art. 25(2) relevant to the new procedures available to overcome infertility? Is the guarantee of adequate health and medical care in Art. 25(1) the basis for a claim of access without limitation to these new techniques?


\(^6\) Supra note 1, at 181.

\(^7\) Justice Warren E. Burger, \textit{Reflections on Law and Experimental Medicine}, in \textit{1 ETHICAL, LEGAL AND SOCIAL CHALLENGES TO A BRAVE NEW WORLD} 211, 211 (George P. Smith, II ed., 1982).
ferring minimized and spiritual tranquility assured.8

The late Professor Thomas Emerson, a great civil libertarian, cautioned in 1976 that one of the hard problems of the First Amendment would soon be acknowledged as the extent to which the state could recognize scientific research.9 As he observed sagely, "It is hard to predict where these issues will lead."10 This essay will explore the pathway where these issues are leading in contemporary society.

Roots of the Modern Conflict

Long before Professor Emerson, Chief Justice Burger and Justice Kirby crystallized their ideas and their predictions, the epic struggle of Galileo was played out and, as such, gave new direction to how scientific freedom of expression would be allowed in 17th century Catholic theology.11

Galileo was censured by Pope Urban VIII in 1633 for averring Copernicanism - the theory that put the sun at the center of the solar system. Summoned to Rome to defend his book written the previous year, DIALOGUE CONCERNING THE TWO CHIEF WORLD SYSTEMS, Galileo failed to sustain his case for free and unfettered scientific inquiry. The views of Copernicus had been censured by Rome in 1616 (even though he actually died in 1543) and, in that same year, Galileo had been warned to cease his study and advocacy of the Copernican theory. Originally condemned to life imprisonment for his views, Galileo's sentence was commuted by Urban VIII to life-long house arrest thus enabling him to return to Florence.12

10. Emerson, supra note 9, at 746-47.
12. Id. It has been suggested recently that Galileo's difficulty was not with his astronomy but his physics because 17th century Roman Catholic theology could more easily tolerate and live with the Copernican system, termed heliocentrism, than with a view of physics whose atomism seemed to challenge the Eucharistic dogma that taught at Communion that bread and wine were, ipso facto, transubstantiated into Christ's body and blood. Id. See also Michael Seore, In the Wake Of Galileo 27 (1991) (Editor's note: this Article was written and edited prior to the October 31, 1992 pardon of Galileo. For a discussion of this
Galileo's legacy is his animation of a movement designed to advance and, indeed, promote freedom of scientific expression. More specifically as to his own case, Galileo fought against the intellectual tyranny of what was termed Aristotelian scholasticism and campaigned for the advancement of a new scientific language that, in turn, would advance a basic right of research and free intellectual discourse against what were prevarications of institutional culture.  

II. OPPORTUNITIES FOR THE NEW BIOLOGY IN AMERICA

Modern scientific work is less a basic expression of the “ancient aristocratic ethos of the love of knowledge” than a mere job to be done by entrepreneurs, employees, or others who have independent funding. In 1980, Genentech, a San Francisco based biotechnology company, issued shares of its stock on the over-the-counter market. Among its products are a hormone capable of stimulating human growth, mass produced human insulin which would allow a substantial reduction in cost of the treatment of diabetes, and interferon which may prove to be the long awaited “miracle” drug to combat cancer. The price of Genentech stock increased dramatically during the first day of trading, and some brokers even suggested that Genentech may in time be the next Polaroid or Xerox. It has been asserted that patenting new forms of life, as sanc-
tioned by the United States Supreme Court,16 will be guided by short term profit motives rather than sound philosophical principles.17 However, scientific knowledge is not, in and of itself, an absolute end. The thrust and purpose of patenting new life forms are basically technological and are essentially political. Because the etiology of new life forms is political, both its costs and its benefits are, of necessity, of public interest and concern.18

Pure scientific inquiry does not produce an economic exploitation of nature; only man's use of the truths of scientific inquiry does. With the methodological style of nature, science seeks to demonstrate causal relations among events. Thus, the laws of science state that whenever X occurs or varies in a particular way, Y will similarly occur or vary in a particular way. This phenomenon has been aptly termed "a formula for action." Its practical application awaits only an individual's decision that it might be economically advantageous to try to mobilize X's to produce Y's.19 Science promises truth, not peace of mind.20 Yet liberty to extend knowledge is never to be regarded as absolute - but rather as has been seen, undergoes limitation when it conflicts with other values.21

The spirit of inquiry and analysis must focus as well on the additional parameters of the scientific imperative to explore truth; with the reality of this inquiry being shaped in turn largely by the United States patent laws and administrative interpretations and, more specifically, by the United States Supreme Court in its holding allowing new forms of life created in a laboratory to be patented. The ultimate purpose of this investigation is to refute the arrogance of power theory expressed as being implicit in the current studies of the vast potential for the positive achievement of good through harnessing the "New Biology." Thus, it will be demonstrated, that what has been dismissed as but a magnificent obsession for power, profits and immortality has, in truth, a far more intrinsic potential

18. Compton, supra note 14, at 37.
19. Id.
for good and reward for the scientific community and the greater world community.

Improvement of man's genetic endowment by striving for positive propagation of those with a superior genetic make-up or, conversely, delimitation of those with negative genetic inheritance has always been a primary concern in the field of genetics. If the quality of life in some way may be improved or advanced by use of law as it relates to genetics, then such must be undertaken. No longer does the Dostoevskian quest to give life meaning through suffering become an inescapable given. By and through new scientific advances in the field of genetics and successes with in vitro fertilization, the real potential exists to prevent, in large measure, much human suffering before it manifests itself in or through life.

Altering Human Evolution

Today, man is in a position not only to alter the social and environmental conditions of the universe, but also to change his very essence. The mythology of the Minotaur and the Centaur, half man and half animal, may well become the reality of the twenty-first century. Indeed, not only is modern medicine attempting to create man-animal combinations, but also man-machine combinations, or cyborgs. Plastic arteries, artificial limbs, and pacemakers highlight the efforts of modern science to replace diseased or worn out parts of the human body.

Efforts to construct or engineer biologically functional bacterial plasmids in vitro exemplify the relatively new technology of recom-


binant DNA. Regarded as the most significant step in the field of genetics since 1953, research in this technology will facilitate identification of every one of the 100,000 genes in the human cell. Armed with this information, efforts could be directed toward replacing defective genes with healthy ones. Thus, the hope is that by making such replacements, genetic diseases such as hemophilia and sickle-cell anemia could be conquered. Indeed, the plenitude of new products of nature that could substantially improve the human condition is staggering to the imagination.

The National Institute of Health (NIH) has taken a conservative view of the limits of safety review required by those institutions receiving federal grant monies to experiment in DNA. In 1980, two hundred representatives from the scientific community called upon NIH to loosen the restriction on gene-splitting experiments conducted in the United States. The scientists expressed the growing agreement that DNA research carries fewer risks than had once been thought.

The central question which arises in relation to the current scientific advances is whether genetic engineering should be promoted and encouraged as a basic recognition of the freedom of scientific inquiry and right of privacy. Significant potential dangers are present in conjunction with the almost limitless opportunity for scientific advancement within the technology of recombinant DNA, commonly referred to as genetic engineering. The fear that the proverbial “mad scientist,” working independently or with an enemy foreign power, could isolate and then proceed to duplicate a cancer organism and possibly place it in public water supplies is not easily dismissed. Acts of thoughtless negligence in a laboratory could result in the “escape” of a deadly microbe, which in turn could give

26. DNA is the basic genetic material that transmits inherited characteristics.
rise to a "parade of horribles." Chance occurrences are always inherent in any scientific intervention. When the chance of harmful accident is calculated, the primary consideration is whether the merit of the intervention justifies beginning or continuing the experiment.

Genetic engineering, viewed as an instrument to revolutionize, limits the effect of natural selection and replaces it with programmed decision making. Programmed decision making facilitates, rather than impedes, rational thinking. Is it shameful to acknowledge that man has the capability to be in control of himself? The lack of control over the years has spawned a type of "evolutionary wisdom" which, in turn, resulted in the bubonic plague, smallpox, yellow fever, typhoid, diabetes and cancer. Today, the quest for maximum efficient utilization of biological and medical knowledge represents one of the tenets of the so-called "evolutionary wisdom."

A number of Post-Darwinians in the scientific community assert that there is no wisdom in evolution, only chance occurrence. Few, if any, would be willing to accept unconditionally all that nature bestows, particularly disease. Consequently, science finds itself in the position of trying to both influence and, in many cases, control the process of evolution. Some would go so far as to suggest that dangerous knowledge is never half as dangerous as dangerous ignorance.

The sanctity of creation and the fundamental right of privacy in procreation, which is an acknowledged basic or fundamental freedom, may be altered by compelling state interests. Is there a more

31. Joseph Fletcher, Ethics and Recombinant DNA Research, 51 So. Cal. L. Rev. 1131, 1139, (1978). Fletcher observes that there is nothing fundamentally unnatural or intrinsically wrong, or hazardous for the species, in the ambition that drives man to develop the technology to understand himself. It would in fact seem more offensive to fail to use and develop man's natural curiosity and talent for asking questions or worse to try to suppress it. "This is the greater danger of our species, to try to pretend that we are another kind of animal . . . and that the human mind can rise above its ignorance by simply asserting that there are things it has no need to know." Lewis Thomas, Notes of a Biology Watcher: The Hazards of Science, 296 New Eng. J. Med. 324, 328 (1977).
33. See Roe v. Wade, 410 U.S. 113 (1973); George P. Smith, II, Procreational Auton-
compelling state interest than the desire to stop a "chromosomal lottery" which saddles the economy each year with four million Americans born with diabetes or fifty thousand born with discernible genetic diseases? \( ^{34} \) State interests in minimizing human suffering and maximizing the social good should be properly validated. \( ^{35} \)

Opponents of unrestricted genetic research specifically attack its proponents as being both scientifically and socially irresponsible, and the ultimate promoters of a serious environmental disaster. \( ^{36} \) They suggest that nature has developed strong barriers against genetic interchanges between species, and that extreme caution ought to be used during experimentation in this area. \( ^{37} \) Others argue that mankind's genetic inheritance is its greatest and most indispensable treasure which must be protected and guaranteed at any cost. These opponents submit that the evolutionary wisdom of the ages must not be irreversibly threatened or abridged in order to satisfy the ambition and professional curiosity of some members of the scientific community.

Autonomy, self-determination, and a basic sense of freedom must be tempered by logic, objectivity, and a disinterested search for knowledge; a search that may result in the minimizing of human suffering and maximizing of social good. \( ^{38} \) But what is the social good in this question? It is suggested that the social good, within this context, could be equated with an economic policy that lessens the financial burden on citizens and supports and maintains genetically defective citizens. The wisest policy is, by consensus, that which promotes a goodsocial, economic or otherwisefor the greatest number. Thus, human need and well-being shape the degree of positive good resulting from one policy as opposed to another. \( ^{39} \) Alternatively, a determination could be made in order to structure what is right or wrong, good or evil, according to whether the consequences of an act or public policy add to, or detract from, the aggre-
gate human well-being.\textsuperscript{40}

Ultimately, the decision for or against a policy is going to be tied to development and maintenance of an \textit{a priori} standard of ethics (where, in theory, a balancing occurred before the standard was set), or to a situational ethic by which the consequences, \textit{pro} and \textit{con}, equities or inequities, of each proposed action will be carefully weighed and a conclusion with an ethical posture or structure of a standard of \textit{modus operandi}\textsuperscript{41} will be reached.

Encouraging Experimentation

Recognizing that a sustained level of progress for society would depend upon a continuing standard of technological evolution as well as individual technological contributions of exceptional merit and benefit, the Founding Fathers endeavored to codify this attitude within the United States Constitution. By structuring a system of checks and balances within the Constitution which would promote both perspectives, contributions which were truly exceptional could be promoted by grant of a limited monopolization as authorized by the Patent Clause.\textsuperscript{42} However, the grant of limited monopolization was intended to be consistent with the guarantees of the fifth and the fourteenth amendments, that recognize the right of all citizens to develop their individual skills in pursuit of a trade or calling, and thus establish this right as an inalienable property right.\textsuperscript{43}

There is a long history of efforts to legitimize monopolies for patents of unworthy inventions. To its credit, the United States Supreme Court has thwarted these efforts and has recognized and enforced the Constitutional mandate to allow the unfettered growth and natural evolution of technology.\textsuperscript{44}

On June 16, 1980, by a 5-4 vote, the United States Supreme Court decided that new forms of laboratory life were eligible for

\textsuperscript{40} See Fletcher, supra note 31, at 1131-39.
\textsuperscript{41} Id. at 1138-39.
\textsuperscript{42} See generally TOM L. BEAUCHAMP & LEROY WALTERS, CONTEMPORARY ISSUES IN BIOETHICS (1978); George P. Smith, II, Uncertainties on the Spiral Staircase: Metaethics and The New Biology, 41 THE PHAROS 10 (1978).
The decision may be regarded as a ratification of some of the accomplishments of the "biological revolution" which has allowed a broader understanding of life and promoted a greater ability to manipulate various forms. However, both the majority opinion and the dissent stressed that they address only the question of whether the current patent laws evinced a congressional intent to deny patents to those inventions determined to be alive. More particularly, the Court chose to tie itself to the United States Code section which provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Out of this statute emerged the issue of whether a manufactured microorganism constituted "a 'manufacture' or 'composition of matter' within the meaning of the statute."

Dr. Ananda M. Chakrabarty, a micro-biologist employed by the General Electric Corporation, engaged in research in which he succeeded in manufacturing a new microorganism, not found in nature, which is effective in breaking up oil spills. This genetically engineered strain of *pseudomonas* is made by combining (or cross breeding) four strains of oil eating bacteria into one man-made scavenging microorganism which combines the beneficial properties of each of its four parent bacteria. Each of the four strains digest particular hydrocarbons in a mixture of oil and water, such as is found in petroleum spills. Useful by-products of water, carbon dioxide and bacterial protein which are nutritious to inhabitants of the ocean, remain. Dr. Chakrabarty demonstrated that this manufactured "superstrain" is much more efficient in digesting oil than a mixture of the four individual bacteria. Another advantage is that this microorganism, if it "escaped," would not be able to thrive in gas tanks or in the oil fields of the earth and wreak uncontrolled

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46. Justice Brennan, writing in dissent, surveyed the Patent Act of 1793, as re-enacted in 1952, the Plant Patent Act of 1920, and the Plant Variety Protection Act of 1970 and concluded that there existed a strong congressional limitation against patenting bacteria. "It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern." Id. at 322. For those who have followed Justice Brennan's judicial philosophy, this position, which calls for judicial restraint, is most interesting and unusual. In the past, he has been the judicial activist and Chief Justice Burger the apostle of judicial restraint. In *Chakrabarty*, the roles were reversed.


environmental havoc on the ecosphere. The Chakrabarty bacterium had already been granted a patent in Britain, which had followed several European nations in recognizing both plants and animals as patentable.

The patent application of Chakrabarty and General Electric was for a manufactured microorganism product not found in nature as well as a process of using the microorganism, on a carrier, to digest oil spilled in water. The United States Patent Office rejected the product claim, but allowed a portion of the process claim. The rationale for rejection of the product claim was that a living organism naturally occurring product of nature as this was determined to be, was not within the classes of subject matter which are patentable. The patent office reached this conclusion because there was no mention of such a class in the controlling statute or in the statute's legislative history. This decision was upheld by the Patent Office Board of Appeals, but the United States Court of Customs and Patent Appeals reversed, and the Patent and Trademark Office appealed to the United States Supreme Court.

In the past, the Patent Office has included living things within the statutory subject matter. For example, in 1873, United States Patent No. 141,072 was issued to Louis Pasteur. Claim two of the patent application reads: "Yeast, free from organic germs of disease, as an article of manufacture." There are other examples, in other patents, of claims having been granted for viruses and cultures.

Today, there are more than one hundred patent applications related to products of genetic engineering. Chakrabarty sets the

pace for a wide variety of new "man-made organisms which can facilitate socially desirable processes such as growing wheat in arid lands, leeching ores to assist mining companies in reaching remote part of the earth, and producing a "bug" that will ferment corn starch or corn syrup into ethanol, an alcohol used in both whiskey and gasohol. There is also a patent application for a bacterium that metabolizes ethylene into ethylene glycol (antifreeze).  

As noted previously, the major thrust of the decision of the United States Supreme Court in Chakrabarty is tied to the interpretation of the term "manufacture" as it appears in the federal patent code. Observing that Thomas Jefferson's Patent Act of 1793 stressed its coverage to "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]," Chief Justice Burger, writing for the majority, defined manufacture as "the production of articles for use from raw materials prepared by giving to these new materials new forms, qualities, properties, or combinations whether by hand labor or by machinery." Citing approving precedent defining "composition of matter" as including "all compositions of two or more substances . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids," the Chief Justice concluded that the Chakrabarty microorganism qualifies as being within patentable subject matter. The claim is particularly forceful since it is for a product of human ingenuity which is non-natural in its occurrence.

In response to the argument that microorganisms cannot be patentable without express congressional authorization, Chief Justice Burger declared that Congress had already defined what was patentable subject matter in Section 101 of the Act, and that it was for

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*Genetic Modification Techniques*, 22 IDEA 113 (1981-82). Some corporations have been quick to market genetically engineered products. For example, DNA Plant Technology Corp. received a patent for a genetically engineered celery, which it calls "Novel Celery Lines With Increased Stick Yield." The patent has been licensed to Freshworld, DNA Plant Technology Corp.'s branded-produce joint venture with Du Pont Co. for use in the Vegi Snax line of snacking vegetables. *DNA Plant Technology Corp.*, WALL ST. J., June 26, 1992 at B6.


56. 447 U.S. at 308 (1980).
57. Id. at 308-309.
58. Id. at 310. See generally, Richard Delgado & Darrel R. Miller, *God, Galileo and Government: Toward Constitutional Protection for Scientific Inquiry*, in 1 ETHICAL, LEGAL AND SOCIAL CHALLENGES TO A BRAVE NEW WORLD 231 (George P. Smith, II ed., 1982).
the courts to define that provision. Finding no ambiguity in the statutory provisions and stressing the broad constitutional and statutory goal of promoting "the Progress of Science and the useful Arts," Chief Justice Burger adhered to his position that the definition the Court gives to section 101 is consistent with the goals of the Act. 59

The Court declined to acknowledge the "grave risks" or the "gruesome parade of horribles" which the Patent Office argued that the Court should weigh in deciding whether the Chakrabarty invention is patentable. 60 Although acknowledging that "genetic" research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of life," the Court concluded that neither the grant nor the denial of patents on microorganisms will end advance in genetic research nor "deter the scientific mind from probing into the unknown any more than Canute could command the tides." 61 The Court stated unequivocally that scientific arguments against advancements in this field are matters of "high policy" which should be considered by the legislative process which balances and places in proper perspective the various competing values and interests of all parties. 62 The Chief Justice concluded by noting that if the Court had misconstrued the provisions of Section 101, all that Congress needed to do was to amend the statute to exclude organisms which are produced by genetic engineering from the protection of the patent laws. 63

Despite the Court's disclaimer that its action was purely constructive in nature merely an interpretation of a statutory mandate it did attempt to validate a new national policy. While invoking the Jeffersonian concept of ingenuity in patent creativeness, it came down four-square on a policy encouraging experimentation into the "New Biology" despite the possible risk to mankind. Thus, while disclaiming the application of a balancing test, it, in effect, performed one. It correctly decided that the utility of the good that will flow from research and experimentation into the varied fields of the "New Biology" far outweighs the potential harm accruing as a consequence of such undertaking. This is an eminently fair and reasonable position.

59. 447 U.S. at 315.
60. Id. at 316-317.
61. Id.
62. Id. at 317.
63. Id. at 311.
A Further Innovative Application

In May, 1987, the United States Patent and Trademark Office announced that it "considers non-naturally occurring nonhuman multi-cellular living organisms, including animals, to be patentable subject matter." This policy was viewed by the Patent Office as an effort to keep pace with the startling new advances in biotechnology, and thereby encourage innovation and not determine its ethical implications. Others, such as animal rights advocates, were concerned that animals were being considered as products and not sentient beings. Some feared that the new policy would enable a select number of biotechnology companies to dominate the livestock industry, thereby eliminating small independent breeders and threatening to eliminate genetic diversity among farm animals, since with patents the central issue becomes who either owns, or is in control of breeding livestock.

Theologians quarreled with the Patent Office policy because it not only equated heavenly made creatures with manufactured goods of the market place, but took a giant step on the slippery slope that would lead to the patenting of genetically altered human beings and man's full assumption of God-like powers. The clear specification of the policy that its application was only for "nonhuman life" was of no assurance here. Informed members of the scientific community, however, saw the Patent Office as merely continuing the reasonable exploitation of nature.

The Transgenic Animal Patent Reform Act was passed in 1988. The Act excludes human beings from patentable subject matter, provides immunity for patent infringement to farmers who purchase patented farm animals and seek to reproduce them, and also seeks to clarify the Patent and Trademarks Office's authority to require biological materials deposits from patented animals. The

65. Id.
66. Id.
68. Id.
69. Id.
most serious defect of this law is that it fails to define the term, "human being." Thus, the extent to which genetic material constitutes a human being is an open question.

"Should an animal that contains one-half of a human code be considered human? How about one-quarter human genetic material? Should genetically altered fetuses be considered patentable subject matter under current patent law? Although such animals are not being patented, . . . such technology will exist in the near future."\(^{72}\)

It is expected that the near future of biotechnology will give rise to work in laboratories in the United States where virus and bacteria genes will be transferred to plants in an effort to enable them to produce their own particular insecticides or fertilizers. After field testing, these "transgenic" plants will be used by farmers in the place of conventional crop varieties.\(^{73}\) Further successful research will be undertaken that manipulates the primordial cells producing sperm and eggs to enable breeders to determine the sex and other preferred characteristics of their animals; and routine gene transplants from one species to another will be accomplished routinely.\(^{74}\)

As discussed previously,\(^{75}\) these and similar concerns over patenting life were initially raised with the Chakrabarty decision.\(^{76}\) Since no catastrophic events have followed in the aftermath of Chakrabarty, and none are expected from this new policy of the United States Patent and Trademark Office, the on-going debates over the long range effects of genetic engineering and its ethical constraints will be of little value in halting the momentum of scientific inquiry, experimentation and advancement of biotechnology.


75. See supra notes 18-41.
III. VALUES IN CONFLICT

Some would seek to abandon science and reason in favor of mysticism, hermeneutics and transcendental rapture. Sadly, they fail to comprehend that ignorance, not knowledge assures misery; and that the employment of science for inhumane reasons, not science in and of itself, threatens global survival. Reduced to its most fundamental level, then, what is seen is that the pivotal questions confronting the science of human experimentation are two in number: who will control its products, and what purposes will be employed to achieve this end.\footnote{77. Joseph Francis Fletcher, \textit{Humanhood: Essays in Biomedical Ethics} 93 (1979). See 1 \textit{Ethical, Legal \& Social Challenges To A Brave New World}, Ch. 10 (G. Smith ed. 1982); see also \textit{Commercialization of Biotechnology: Hearings Before the Subcomm. on Technology and Competitiveness of the House Comm. on Science, Space and Technology}, 102 Cong., 1st Sess. 70-75 (1991) (statement of Lawrence Busch, Michigan State Univ.).}

The improvement of human well-being has been, for the most part, the single motivating force in the quest to ensure that all citizens, especially young children, will be safe from all forms of disease; not only genetic and congenital disorders, but uterine infections and a formidable host of other birth defects.\footnote{78. \textit{Id. See also} Eisenberg, \textit{infra} note 114.} Since the 1930s, for example, human fetal tissue has been an invaluable research tool for molecular biologists as a source of human cell lines. In turn, these cell lines have been widely used in advanced research on viruses, and in the preparation of vaccines (notably, the polio vaccine) against them. More recently, successful research has been conducted on fetal tissue transplants in living subjects for therapeutic purposes, and for developing treatments for Parkinson's disease, diabetes and radiation-induced anemia. What makes fetal tissue so particularly useful for transplantation is the fact that it not only grows rapidly and is very adaptable, but induces a limited immune response from the host.\footnote{79. Henry Greely et al., \textit{The Ethical Use of Human Fetal Tissue in Medicine}, 320 \textit{New Eng. J. Med.} 1093 (1989). It is between the sixth and eleventh weeks of gestation that nearly eighty percent of all individual abortions are performed. Thus, neural and other tissue are at a sufficiently developed state that it may—with success—be retrieved and transplanted. For those abortions performed between fourteen and sixteen weeks, pancreatic tissue is of particular value in diabetes research. John A. Robertson, \textit{Rights, Symbolism and Public Policy in Fetal Tissue Transplants}, \textit{Hastings Center Rep.}, December 1988, at 5.}

The Federal Position

Both as a response to Louise Brown's extracorporeal birth in
1978, and to a grant application for in vitro fertilization (hereinafter "IVF") research, the then Department of Health, Education and Welfare (now the Department of Health and Human Services) and its Ethics Advisory Board decided to study the complex ethical, legal, social and scientific issues raised by the IVF process. The final report of the Department was ultimately "buried in the bureaucracy." Yet today, given the sometimes strident pro-life mood of a vocal segment of society, there is pessimism that a strong positive movement will occur at the federal regulatory level. Due largely to the leadership of former Congressman (now Senator) Albert Gore of Tennessee, hearings were conducted in August, 1984, on the issue of embryo transfers and the legal, ethical and medical responses to such procedures. Although no firm or conclusive steps were taken as a consequence of these hearings, they served to focus attention on the need for continuing dialogue in this area.

Because of a de facto moratorium set in 1975, no federally funded research has been undertaken on IVF. Even though the 1979 Report of the Ethics Advisory Board of HEW concluded that federal support of research on humans designed to establish the safety and the effectiveness of IVF procedures would be ethically permissible so long as certain conditions were met, the Report has never been accepted nor the moratorium ended; there is no real likelihood such action will be taken soon.

It should be noted that the involvement of the federal govern-

82. This pessimistic, although realistic, view is tied to a perception that it would be far better to hold in abeyance any strong movement at this time for fear of its possible linkage with the right-to-life controversies and would thus give rise to the real possibility that it would never be allowed to be evaluated in a calmer atmosphere. Susan Abramowitz, A Stalemate on Test-Tube Baby Research, HASTINGS CENTER REP., February 1984, at 5.
84. Abramowitz, supra note 82.
85. Ethics Advisory Board, supra note 80 at 35,057. Among these conditions were that the embryo be sustained in vitro beyond the implantation stage and that IVF, followed by embryo transfer, be used only by married couples who had donated their sperm and ova. Abramowitz, supra note 82.
ment and its Department of Health and Human Services is presently structured by general regulations protecting human subjects which apply to any IVF research, development, or other related activities that might in the future be conducted by the Department, or by the federal government outside the Department. To ensure additional protection in research projects that involve fetuses and/or pregnant women, the Ethics Advisory Board of the Department will be required to review every such proposal for IVF "as to its acceptability from an ethical standpoint."

Subsequent specific protections have been provided to fetuses who are the subject of proposed experimentation and IVF research. Although limited to research efforts funded in whole or in part by the federal government, these guidelines make a significant distinction with regard to potential legal rights of implanted embryos. The distinction is apparent in the definition of a fetus as "the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test...)."

As a consequence of this structured definition, research undertaken on fetuses in utero and ex utero is prohibited unless the purpose of the activity is to either meet the particular health needs of the at-risk fetus, or there is minimal real or potential harm to the fetus by the research, and the purpose is to obtain biomedical knowledge not otherwise obtainable. Research undertaken on non-viable fetuses ex utero is prohibited unless either vital functions will not be maintained artificially, experimental activities that would terminate vital functions are not used, or the research purpose is to obtain otherwise unobtainable significant biomedical knowledge. The obvious implication of these restrictions on embryonic and fetal research is that the scientific pursuit of mankind is significantly handicapped. Private research into the mysteries and the opportunities of the new reproductive biology continues. But,

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89. 45 C.F.R. §§ 46.102-206 (1985). In Vitro Fertilization is defined as "any fertilization of human ova which occurs outside of the body of a female, either through admixture of donor human sperm and ova or by any other means." Section 46.203(g) (1991).
without a balanced regulator scheme and sources for federal research funding, the initiative and the momentum for scientific advancement is curtailed.

The Bush Administration Extension

On November 13, 1989, the Bush Administration, through Dr. Louis W. Sullivan, Secretary of Health and Human Services, advised the National Institutes of Health that, because of a belief that allowing federal scientists to conduct research using fetal tissue transplants would actually increase the incidence of abortion across the country, the ban on fetal-tissue research would be extended. The Secretary stated that his department "should not be funding activities which encourage or promote abortion." Even though limited in application to federal scientists, many members of the medical research community are of the opinion that extension of the fetal tissue research ban will produce a "chilling-effect" on this exciting field of research even for privately funded undertakings. What is seen very clearly here is the inextricable relationship between abortion, fetal research and experimentation and, even more importantly, a similar inextricability between politics and morality.

A British Response

A more sophisticated and enlightened position has been taken by the British Government. In response to the findings of a national committee set up in 1988 to review guidelines for research use of fetuses and fetal material, the British Health Minister announced

95. Michael Specter, Fetal-Tissue Research Ban Formally Extended, WASH. POST, Nov. 3, 1989, at A5. (Editor's note: President Clinton has promised to lift the ban).
96. Id.
98. Id. Assistant Secretary of Health James O. Madison at the Department of Health and Human Services, told a congressional hearing April 1, 1990, that if the federal ban on funding of medical research using fetal tissue were lifted, women would be encouraged to have abortions. He observed that should the transplantation of fetal cells prove successful in treating epilepsy, diabetes and Parkinson's disease, "additional rationalization of [for] directly advancing the cause of human therapeutics cannot help but tilt some already vulnerable women toward a decision to have an abortion." Malcolm Gladwell, HHS Official Defends Fetal-Tissue Policy, WASH. POST, April 3, 1990, at A3.
that the Government had accepted the central recommendations of the Committee which were issued July 26, 1989. Separating abortion from the issue of how tissue from a dead fetus should be used, the Committee recommended that separate maternal consent be obtained for any act of abortion, and for the use of tissue from an aborted fetus. No direct contact would be permitted either between the abortion clinics or the institutions utilizing the tissue for research. In an effort to safeguard against a possibility of “personality transfer” between a fetus and the recipient of fetal brain tissue, the recommendation was that in particular cases of nervous tissue, “only isolated neurons or fragments of tissue should be used for transplantation[8].”

The British Medical Association promptly endorsed the recommendations and the government posture, observing that this policy was totally compatible with what the members of the Association had freely “adopted covering physicians responsible for carrying out abortions, as well as those using fetal tissue to develop new therapies.”

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101. Dickson, supra note 100.

102. Id.

103. Id. The British Medical Association supports the following recommendations:

1. “Tissue may be obtained only from dead fetuses resulting from therapeutic or spontaneous abortion. Death of the fetus is defined as an irreversible loss of function of the organism as a whole.

2. UK laws on transplantation must be followed. The woman from whom the fetal material is obtained must consent to the use of the fetal material for research and/or therapeutic purposes.

3. Transplantation activity must not interfere with the method of performing abortions, nor the timing of abortions, nor influence the routine abortion procedure of the hospital in any way. Abortion must be performed subject to the Abortion Act, and any subsequent amendments thereof, uninfluenced by the fate of the fetal tissue. The anonymity of the donor should be maintained.

4. The generation or termination of a pregnancy solely to produce suitable material is unethical. There should be no link between the donor and the recipient.

5. There must be no financial reward for the donation of fetal material or a fetus.

6. Nervous tissue may be used only as isolated neurones or tissue fragments for transplantation. Other fetal organs may be used as either complete or partial organs for transplantation.

7. All hospital staff directly involved in the procedures—including the abortion—must be informed about the procedures involved.” Supra note 95, BMA Guidelines.

In a free-vote on April 25, 1990, the British Parliament endorsed the continued practice of conducting in vitro medical and scientific research and experimentation on human embryos up to 14 days of age. It is commonly understood that the appearance of the “primitive streak” that represents the first physical embodiment of individuality, takes place the 14th day after fertilization. Experiments on human cloning and hybridization (or the creation of human-animal hybrids) were, however, outlawed. Michael White & Patrick Wintour, Britain
Since, like it or not, abortion is legal, is it not a simple deduction that it is ethically acceptable to use tissue from abortuses for research? Rational, simple deductions are not the order of the day, however, when dealing with issues that are so emotionally charged. Inexplicable "feelings" and beliefs assume a mantle of sanctity not countenanced in other logical areas of discourse. It is nevertheless a legitimate act of faith to postulate that fetuses are persons. The only difficulty with such a position is that there is no absolute way to prove or establish its validity. It can neither be verified nor falsified.

A New Initiative?

Under a Bill entitled, "The National Institutes of Health Revitalization Amendments of 1991," introduced by Congressman Henry A. Waxman on March 20, 1991, the moratorium on federal funding of research on transplanting fetal tissue would be overturned. The bill provides that the National Institutes of Health, by and through the authority of the Secretary of Health and Human Services, would be given permanent authority to fund such research, provided that it complies with strict ethical guidelines prohibiting the sale of fetal tissues or directed donations. The proposed legislation would preclude the Secretary from issuing a refusal to fund research determined to be scientifically valid on purely ethical grounds, unless a special ethics advisory panel first agreed that the research was unethical.

Before research could be undertaken on donated human fetal tissue, the woman providing the tissue must execute a written statement acknowledging that the fetal tissue is being donated for use in authorized research; that the donation is to be made without regard to the identity of individuals who may ultimately be the recipients of the tissue; and that the female donor has not been informed of the identity of any recipients. In cases where tissue is provided as a

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104. This was the initial posture taken by a review panel of the United States National Institutes of Health and presented to the then Assistant Secretary for Health, Robert Windom in 1988. Dickson, *supra* note 100.

105. Fletcher, *supra* note 77 at 96.


108. *Id.* § 101.
consequence of an induced abortion, the donor’s statement must acknowledge that the decision to donate is made independent of the abortion decision, and not for the purposes of providing fetal tissue for research.\textsuperscript{109}

If enacted into law, this proposed legislation would help to harmonize the needs of science with individual human rights. With the moratorium on fetal research and experimentation lifted, handicapped individuals with genetic or other disease, would no longer be told that the cure for their disease is “too controversial to study” or “too political to pursue.”\textsuperscript{110}

IV. TOWARD A STANDARD OF REASONABLENESS

The Supreme Court’s actions in \textit{Chakrabarty}, and the recent Patent and Trademark policy on the patentability of nonhuman life, give private corporations the incentive to invest further research into the fields of bio-chemistry, genetics, and eugenics. This incentive, and the anticipated result therefrom, satisfy the constitutional objective of early disclosure which expands the public domain of knowledge in these fields. There can be little doubt that patentability of microorganisms and nonhuman life forms is “Progress of the Useful Arts.”

Man’s dehumanization and depersonalization will not be fostered as a consequence of the continued quest for mastery of the genetic code, and the study and use of non-coital reproduction processes. Attendant to the freedom to undertake research into the exciting and fertile frontiers of the “New Biology” is a coexistent responsibility to pursue the work in a reasonable and rational man-

\textsuperscript{109} Id. § 111. H.R. 1532 was substituted and replaced by H.R. 2507 amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health and passed the House on July 25, 1991. The central focus of the replacement bill parallels the original H.R. 1532. \textit{See} \textit{CONG. REC.} (daily ed. July 25, 1991) H5879. Senator Ted Kennedy introduced S.B. 1523, parts of which in addition to dealing with NIH re-authorization, consider ways to modify the ban on fetal experimentation. The Senate passed the measure 83-14 on June 4, 1992. However, it passed the House by only 260-148, short of the two-thirds necessary to override a presidential veto. President Bush vetoed the measure on June 23, 1992 explaining he vetoed it “to prevent taxpayer funds from being used for research that many Americans find morally repugnant and because of its potential for promoting and legitimizing abortion.” Adam Clymer, \textit{Bush Vetoes Allowing U.S. To Fund Fetal-Tissue Study}, N.Y. TIMES, June 24, 199 at A13. Critics were quick to point out that politics had a lot to do with the veto. Robert Bazell, \textit{Tissue Issue}, \textit{THE NEW REPUBLIC}, June 29, 1992 at 10 (Bush offering millions of sick and desperate Americans an “enduring civic lesson”); \textit{but see} Louis W. Sullivan, \textit{Good Reason for the Fetal-Tissue Research Ban}, \textit{WASH. POST}, Aug. 16, 1992 at C6 (Secretary Sullivan defends ban).

Pursuing the “New Biology” in such a manner requires adequate attention to the safety factor in all aspects of the experimentation. The undesirable events of a Brave New World can be tempered only when knowledge is pursued with the purpose of establishing the truth and integrity of the question, issue, or process. The vast potentials for advancing society and ridding it of a verisimilitude of its present ills is an obvious good which must be steadily pursued. Little sustaining harm can result from a reasonable pursuit of truth and knowledge; for, indeed, truth and knowledge are the basic interstices in any balancing test. If actions are undertaken and performed with the goal of minimizing human suffering and maximizing the social good, then the noble integrity of evolution and genetic progress will be preserved.

So long as procreation continues to remain a central driving force in a marital relationship and the family the very core of a progressive society, efforts will be undertaken to expand the period of fecundity and combat infertility. Genetic planning and eugenic programming are more rational and humane alternatives to population regulation than death by famine and war.

Man must endeavor to execute his investigatory and manipulative or creative powers within the scientific laboratory with a rational purpose and in a spirit of humanism. Man should seek to minimize human suffering, thereby contributing to the social goal of allowing each member of society an equal opportunity to achieve their maximum output within the economic marketplace, and to maintain personal integrity and seek spiritual tranquility. Genetic engineering that contributes to the social good should be utilized fully. There can be no real doubt that genetic manipulation provides a perilous opportunity that may either threaten freedom or enhance it; depending upon the balance struck between its use for...


individual need satisfaction and societal good.\textsuperscript{114}

Restraining scientific inquiry, to my way of analysis, should be limited only to action considered to be unreasonable. Accordingly, an undertaking would be regarded as unreasonable when the long and short term costs of its effects would outweigh the enduring benefits that would derive from its study and implementation. Viewed, then, as being not only an aid to the tragedy of infertility in family planning, but as a tool for enhancing the health of a nation's citizens, vital scientific research must continue in the new, non-coital reproductive technologies and in efforts to engineer man's genetic weaknesses out of the line of inheritance. Healthier and genetically sound individuals have a much better opportunity for pursuing and achieving the "good life" and making a significant contribution to society's greater well being.
