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DNA Technology: Are We Ready?

I. *Introduction*

It is a common practice to identify certain historical periods with the name of the most significant technological invention of the time. Thus, we have had an Industrial Revolution, an Age of Steam, the Automotive Age, and so on, up to the Atomic Age. We are now at the crossroads of a new age; the Age of Biology.

This new age promises to be every bit as influential in terms of broad social impact as any of its predecessors, and may ultimately profoundly modify the way in which we define our lives. The hallmark of this new age is DNA technology, the ability to manipulate the genetic make-up of living organisms; and like most new techologies, this one must be treated with respect in order to maximize the benefits while minimizing the attendant disruptions and risks. The purpose of this article is to explore alternative ways of dealing with DNA technology, and to recommend a safe as well as workable course of action.

II. *Background*

Biological Background

In 1953, James D. Watson and Francis Crick first described the molecular structure of deoxyribonucleic acid, DNA, the carrier of the genetic codes that determine the myriad functions of life.[1] This discovery was the forerunner of a whole new biological technological explosion. This new science is still in its infancy, but has nevertheless grown over the past decade to the point where molecules of DNA have been taken apart, modified, and recombined, termed Recombinant DNA. This achievement is of such magnitude that it has been termed "as significant as the splitting of the atom".[2]

DNA can be visualized as a spiral ladder of two complimentary

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*R. H. Guthrie, LL.B. Dalhousie, 1981.

1. R. Gore, *Exploring the New Biology* (1976), 150 National Geographic 355, at 359

2. R. Sinsheimer, Chairman of the Biology Division of Cal Tech., before the U.S. Senate Health subcommittee, reported in (1977) 194 Science 303

strands of chemical compounds called nucleotides.[3] There are four of these; adenine, thymine, cytocine, and guanine, abbreviated A,T,C, and G respectively. The nucleotides in each strand line up end to end like so many box-cars, and they compliment each other sideways, so that T is always opposite A, and C is always opposite G. Thus, a segment of DNA could be shown as:

- A - T - T - C - G - A - A - G - T -
- T - A - A - G - C - T - T - C - A -

with the physical attraction between the two strands being indicated by the dots.

Units of nucleotides are called *genes,* each of which contains the information for a specific function of the cell, and which may contain as many as ten thousand letters. Groups of genes are united to form *chromosomes,* which may contain many thousands of genes. The total gene compliment of the cell is called the *genome.*

The transmission of essential genetic information between generations depends upon precise replication of the nucleotide sequences of DNA. Under appropriate conditions, the affinity between the two strands reduces, so that they unwind and separate. Free nucleotides line up next to their opposite number (*i.e.* G opposite C; A opposite T) and are coupled end-to-end by an appropriate enzyme. When the process is complete, there are two identical helices.

Plasmids: Apart from the DNA contained in the cell, there are self-replicating loops of DNA called plasmids that can be maintained in the cell independently of the host chromosomes. These plasmids impart certain characteristics or abilities to the cells, which abilities are then transmitted to daughter cells when the host cell divides.

Viruses: Viruses are parasitic organisms which contain their own genetic information, but which require a host cell for growth and propagation. The viral genome may react in the cell in different ways; replicating to form new virus particles which eventually are

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3. The description that follows is generally garnered from the Medical Research Council of Canada's *Guidelines for Handling of Recombinant DNA Molecules and Animal Viruses and Cells, 1977,* ch. 1, catalogue number MR 21-1/1977, ISBN 0-662-00587-2, hereafter called MRC guidelines 1977. See also C. Grobstein *The Recombinant DNA Debate* (1977), 237 Scientific American 23, at 23-25; and National Geographic, *supra* note 1, at 365-367

released, often killing the cell in the process, or trading genetic material with the host genome, which may turn influence the function of that cell when it replicates.[4]

The Technology

As a way of improving on nature, genetic engineering is not a new idea. Selective breeding in animal husbandry has probably been practiced since man first domesticated animals. What is new, however, is the use of micro-organisms to do the job.

Plasmid Transfer: During the early 1970's, Dr. Andra M. Chakrabarty of General Electric's Research Centre was investigating the oil digesting characteristics of certain naturally occuring bacteria.[5] He chemically separated the function-causing plasmid from four such micro-organisms (each of which had a separate oil-disintegrating characteristic) and implanted all four plasmids into a *Pseudomonas* bacteria that could reproduce with all four plasmids intact. The resultant "super bug" digests the four main components (hydro-carbons) of crude oil, leaving the by-products of water, carbon dioxide, and bacterial protein, and is not only commercially feasible as an answer to oil spills, but has been patented in the U.K. and in the U.S.[6]

Recombinat DNA: More basic, although not necessarily more sophisticated in terms of technical difficulty, is the restructuring of DNA itself.[7] Certain enzymes called "restriction enzymes" attack and cut DNA at specific sequences so as to leave overhanging, single stranded, sticky ends. Each particular enzyme is remarkably specific, and cuts DNA only in its own peculiar way, always leaving the same sticky ends. Thus[8] for one of the restriction enzymes commonly used (E co R1) the sequence

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- A - T - G - G - A - A - T - T - C - T - A - A -
    .   .   .   .   .   .   .   .   .   .   .   .
- T - A - C - C - T - T - A - A - G - A - T - T -
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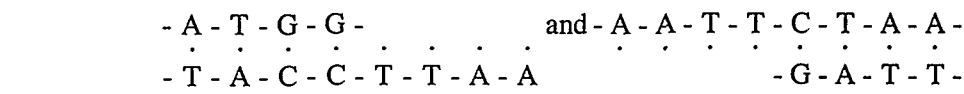
4. There is considerable evidence that such viral genomes contribute to the formation of cancer in several different types of animals, *MRC Guidelines 1977,* at 3
5. *Supra* note 1, at 374-375
6. *Commissioner of Patents and Trademarks* v. *Ananda M. Chakrabarty* (1980), 48 U.S. Law Week 4714
7. *Supra* note 3
8. MRC Guidelines 1977, at 9

is cut so as to produce



Since all DNA molecules from living systems are likely to contain this sequence at some point along their length, it is possible to take DNA fragments from dissimilar organisms and mix them. The overhanging (sticky) ends of the fragments lock together and form a single loop of recombinant DNA, now termed a vector.

The next step is to put the vector into a suitable host organism. This is usually accomplished using a common and thoroughly genetically mapped intestinal bacterium, *Escherichia coli (E coli)*. In addition to its single large chromosome, *E coli* contains one or more plasmids. Typically, it is these plasmids which are isolated from the bacteria, broken open by restriction enzymes, and used as one side of a vector. After the "foreign" DNA has been introduced and the DNA loop closed, the plasmid or vector is returned to the cell. This procedure results in a strain of bacteria that will exhibit genetic characteristics derived from the implanted DNA and which will reproduce independently and truly.

The above describes only part of the technology. To be of any use it is important to be able to isolate and replicate specific sequences coding for desired functions. This can be done in either of two ways. In the first, the DNA sequence responsible for a certain function, for example the production of insulin, is identified and purified, then used in a recombinant vector and placed in a host. This method has the advantage of being safe, in that the experimenter is aware of what is happening at all times, but has the corresponding disadvantage of being rather tedious.

In the second method, all the DNA from the desired function organism is fragmented by enzymes. The fragments are randomly introduced to vectors, and then colonies of host cells to which these vectors have been introduced are cultured. The experimenter picks from the many thousands of host colonies so produced the ones which carry or exhibit the desired abilities. This method has been dubbed the "shotgun" approach, and is potentially considerably more dangerous than the first method. Since the DNA used is impure and uncharacterized, the fragment containing the desired DNA (or host colony exhibiting the desired function) may also carry

undesirable or even pathogenic genes which though controlled in the original cells, could be free to reproduce in the new organism.

Potential Benefits

DNA technology allows the brightest hope for efficient mass production of many of the compounds and products required for the treatment of human diseases and which at present can only be produced by extraction from animal and human tissues. A prime example is the production of insulin. Long the subject of intensive research, insulin was recently successfully fabricated by scientists of the National Research Council, using recombinant DNA technology.[9] While as yet there is no industrial production using this technique, it would seem to be only a matter of time. Certainly there is a ready market; there are an estimated 200,000 diabetics in Canada requiring insulin daily.

Similarly we should see very soon the commercial production of human growth hormone (which controls growth rates in humans. The lack of this hormone causes "pituitary dwarfs".) and interferon, an anti-viral agent which may be a cure for certain kinds of cancer.[10]

Further, there are experiments in the agricultural field that could have wide reaching effects. Scientists are experimenting with such ideas as drought-resistant corn, borrowing the drought-resistant properties of sorghum, and wheat that has borrowed nitrogen-fixing genes from either bacteria exhibiting that property or from the nitrogen-fixing legumes.[11] In general, while many potential benefits cannot as yet be realized, and further developments of technique may be required, there does not seem to be any theoretical limitation to the full and wide-ranging application of DNA technology.[12]

The Hazards

In 1974, in a letter sent to *Nature Magazine* in Britain and *Science*

9. The Mail-Star (Halifax), Thursday, 10 Apr. 80.

10. Biogen S.A., a Swiss firm specializing in recombinant DNA techniques, announced in Jan., 1980, that it had induced bacteria to produce a facsimile of human interferon. Without such technology, production of interferon is incredibly painstaking. CAL Tech scientists estimate that at todays prices and technology, a pound of pure interferon would cost between $10 billion and $20 billion. *Time,* March 31, 1980, at 47

11. *Supra* note 1, at 390

12. MRC Guidelines 1977, at 14

Magazine in the United States[13], eleven members of the National Research Council, National Academy of Sciences, declared a moritorium on recombinant DNA research and urged all scientists working in the area to join them, until such time as ". . . attempts have been made to evaluate the hazards and some resolution of the outstanding questions has been achieved."[14]

The hazards they envisioned were many. One of the most frequently used host organisms in recombinant DNA experiments is *Eschericha coli (E coli),* a bacteria that inhibits the human gut. *E coli* is an ideal host in that it is probably the most researched bacteria in the world, with a thoroughly mapped genome[15], and yet to use this organism is surely asking for trouble. E. Chargaff, Ph.D. professor *emeritus* of biochemistry of Columbia University, writes, "It will eventually get into human beings and animals despite all the precautions of containment."[16] There has already been one near miss. In 1975, A. Chakrabarty, a microbiologist at General Electrics' Research and Development Centre, put together an *E coli* bacterium containing the gene for cellulase, an enzyme that breaks down cellulose. Cellulose is indigestible to humans, and gives bulk to the feces. Should the modified *E coli* infest the human gut, the result could be chronic and even fatal diarrhea. Because of this, the bacterium was destroyed.[17]

Hazards are also envisioned if the presence of recombinant DNA in the host cell confers upon it the capacity for more rapid growth or greater survival. This problem is particularly evident as regards antibiotic resistance in bacteria, which phenomenon occurs naturally in high contamination areas like hospitals, where new pathogenic strains of bacteria that have acquired resistance to specific antibiotics are constantly appearing. Care must be taken that any escaped host and vector do not add the spread of antibiotic resistance.[18]

Most fundamental, however, is the fear of the unknown. We simply do not know what will happen. R. L. Sinsheimer of the

13. P. Berg *et al., Potential Biohazards of Recombinant DNA Molecules* (1974), 183 Science 303. See also *Nature,* 19 July, 1974
14. *Science, ibid.* at 303
15. M. Kukin, *Research and Recombinant DNA,* New York State Journal of Medicine, Feb. 1978 at 228
16. *Ibid.* at 228, quoted from *Fruits of Gene juggling: blessing or curse?,* M. World News 17:45 (Oct. 4) 1979
17. N. Wade, *Dicing with Nature: Three Narrow Escapes,* (1977), 195 Science 378
18. MRC Guidelines, 1977, at 15

California Institute of Technology has been quite outspoken in this regard. In June, 1976, at the University of California he said:

> I do fear that there are potentially grevious risks — of the spread of slow viruses, or of cancer, or of new pathogens yet unborn, evolved from our inventions.[19]

Further, noting the fundamental difference between the simple prokaryotic organisms like bacteria, which have a free floating chromosome and no nucleus, and the complex eukaryotic cells like human cells, with a nucleus bounded by a membrane containing a number of far more complex chromosomes, he postulates a genetic barrier behind which the eukaryotes have developed their more complex mechanisms of genetic control. To transfer these mechanisms, possibly the key to the evolutionary success of the eukaryotes, to prokaryotes, may introduce incalculable evolutionary damage. The prokaryotes may be made far more effective as competitors and parasites, negating an ancient evoluntionary strategy.[20]

However dangerous, the research is ongoing. The self-imposed moratorium lasted only long enough to hammer out some basic research guidelines.[21] There is a good deal of controversy over the extent of the danger presented by the research, and many scientists feel that the original fears of "Andromeda strain"[22] type epidemics were overstated. B. Davis, Professor of Bacterial Physiology at Harvard Medical School states:

> I conclude that while the proposed kinds of experiments present a small but finite danger of causing laboratory infection, the danger to the public is infinitesimel and does not warrant current public anxiety. While the present NIH guidelines are a reasonable response to that anxiety, they are an excessively restrictive response to the scientific realities.[23]

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19. *Supra* note 2, at 304
20. Scientific American, *supra* note 3, at 28
21. In February, 1975, the International Conference on Recombinant DNA Molecules was held in the United States at Asilomar, on the Pacific seaboard. See Berg, *Asilomar Conference on Recombinant DNA Molecules* (1975), 188 Science 991. Subsequently the National Institute of Health (NIH) released guidelines in June 1976, 41 Fed. Reg. 27911 (1976) (hereafter cited as NIH Guidelines). Similar guidelines were proposed in Britain by the Williams Working Party on the Practice of Genetic Minipulation in August, 1976, and the Genetic Manipulation Advisory Group (GMAG) was established in December 1976. Canada followed suit with the MRC Guidelines, *supra* note 3, in 1977.
22. *The Andromeda Strain,* science fiction by M. Crichton, about a "super virus" that destroys the worlds population.
23. *Supra* note 15, at 229, quoting from a paper, *Natural Selection, Viralance and*

The problem now, therefore, is to decide what is the appropriate response to take.

The remainder of this paper will explore some of the possibilities.

III. *Controlling DNA Technology*

Traditional Approach: Do Nothing

The common law's traditional approach to potential problems is to "do nothing", and to wait for the problems to define themselves before looking for solutions. For individual actions arising out of DNA technology, this may be an acceptable solution. The machinery for handling tort and contract problems is well established, and even if the subject matter is novel, the principles of relief are fairly well established. There are, however, serious deficiencies in such an approach.

First, in the traditional tort action, liability is based on negligence, which is defined as, "conduct . . . which falls below the standard established by law for the protection of others against unreasonable risk of harm".[24] The problem is that for DNA technology, there is as yet no well defined "established standard" for the reasonably prudent DNA researcher.[25] Even were this well defined, one questions whether traditional "negligence" and "reasonableness" concepts should be the standard against which accidents arising from this technology should be judged. One can imagine sufficient difficulties in proving causation. Given the already-voiced concerns over unforseeable consequences, the fact that the accident could be proven non-negligent should be irrelevant.[26] One gravitates naturally, in this case, towards the concept of absolute liability.

Communicability, presented in 1977 to the National Academy of Sciences Focus on Research with Recombinant DNA.

24. (1934), Restatement of Torts 282

25. See *Recombinant DNA,* (1977), 11 Georgia Law Review 785 at 813-815

26. In fact, it is the "non negligent" or "impossible" accident that we should fear, and against which we must protect ourselves. In *Roe* v. *Minister of Health,* [1954] 2. Q.B. 66, invisible cracks in ampoules of the anaesthetic nupercaine had allowed the anaesthetic to become contaminated by the phenol solution in which the ampoules were stored. Two patients on which the contaminated nupercaine was used were permenantly paralysed from the waist down as a result. There was no question of causation, but the hospital and doctors all escaped liability. No one had acted negligently, nor had any of the normal precautions been omited, so by traditional tort law, no liability attached. Such a finding keeps legal theory clean and neat, but one wonders if, under the circumstances, the onus has not been placed on the wrong shoulders.

Further, the biohazards feared go beyond concerns of individual injury, and focus on accidents which affect whole groups of people in some major, catastrophic way. There have been analogous occurrences in the past, such as the Thalidomide disaster of the late 1960's. To leave the victims of such misfortune totally at the mercy of traditional tort law is often to appear barbaric and unsympathetic, and yet there is rarely any alternative.[27] This is not to say that the traditional approach is always wrong. Tort law is a tempered tool that has and shall continue to serve us well. But given our ability to forsee consequences and potentially grevious situations, such as with the DNA technology confronting us now, one envisages policy decisions which specifically address questions like apportionment of loss. For the policy makers to leave these decisions to the courts appears not only to be an abdication of responsibility, but considering the potential magnitude of the problem, an unconscionable decision for rational human beings.

Total Prohibition

At the opposite end of the spectrum of possible responses, there is the possibility of total prohibition. While questions about just such a solution have been seriously asked[28], prohibition is not considered a feasible proposition: the potential benefit of DNA research are too great, and the dangers are seen as too small for prohibition to be effective, even if it were not next to impossible to enforce. It is felt that prohibition of DNA research would meet with the same success as did the liquor prohibition of the 1920's, and as does the ban on marijuana today.

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27. See generally, H. Teff and C. Munro, *Thalidomide: The Legal Aftermath,* (1976) Thalidomide was manufactured and licensed in England by Distillers Company (Biochemicals) Limited. As it slowly became apparent that the drug did cause birth defects, 62 writs of negligence were issued against Distillers within the 3-year time limit for such actions (running from the date of birth of the child). The subsequent legal controversy centered around whether or not Distillers had actually been negligent in marketing the drug. The end result for these first 62 claims was a settelement (in which all claimants had to agree) of 40% of the average total amount that would have been awarded had negligence been proven. As part of the settlement the allegations of negligence were dropped. There were other claims, both in Britain and in other countries and settlement amount varied. On the whole, however, one feels that the victims remained just that: victims to the end.

28. *Supra* note 15, at 230, quoting, L. F. Cavalieri, *New Strains of Life — or Death, New York Times Magazine,* 22 Aug., 1976

Viable Approaches

In a paper dealing with the legal mechanisms that will be required to face the DNA Biohazard,[29] T.A. Balmer has suggested that the following elements should characterize an appropriate response:

(a) *Comprehensiveness* — that is, applying to all research;

(b) *Flexibility* — so that any standards set can be quickly changed to reflect up-to-date knowledge;

(c) *Detail* — so that the precautions required are realistic and match the hazard;

(d) *Participation* — that is, that as the hazards are not limited to the scientists that perform the experiments, deciding to take the risks is not merely a scientific question, but one requiring public awareness and imput.

These characteristics appear to be well founded. However, one over-riding characteristic should be added: so far as humanly possible, keeping in mind the need to control, but not to control to the point of stifling, the system set up to handle DNA technology and the attendant hazards must work!

With these considerations in mind, let us review and evaluate what has already been done.

Guidelines

As discussed earlier, the results of the moritorium letter and the Asilomar conference[30] have been guidelines which attempt to regulate DNA experimentation. These must be viewed as a serious and commendable attempts to deal with the potential hazards, but one wonders if they are sufficient.

Canadian guidelines propose both physical and biological containment for experiments, and in fact go farther than the American or British counter-parts, in that they apply to animal viruses and cells, as well as to Recombinant DNA Molecules.[31] However, the guidelines themselves are the product of the scientific community. While this is not necessarily bad, and does not necessarily imply a conflict of interest, still one should retain a health skepticism. Scientists may not be the best judges of the controls to be placed on their own professional pursuits. Sinsheimer

29. Balmer, *Recombinant DNA: Legal Responses to a New Biohazard* (1977), 7 Environmental Law 300

30. *Supra* note 21

31. In June 1979, MRC published revised guidelines, Cat. No. MR21 — 1/1979, ISBN 0-662-50256-6

explains "Scientists can be very insular . . . you have to believe what you are doing is good and beneficial."[32] One questions seriously, for example, the continued use of *E. coli* strains as host-vectors, in spite of the biological weakening of this bacteria.[33]

As well, the present guidelines do not fully cover the hazards. For example, Chakrabarty's experiments involving, as they do, plasmid transfer rather than recombinant DNA technology[34] are not covered. However, because of the robustness of such bacteria (due to their commercial application) they may present a greater hazard than recombinant DNA molecules.[35]

Of major concern is the lack of enforceability of the guidelines. While the Principal Investigator and the local biohazard Committees are responsible for seeing that the guidelines are followed[36], the sole sanction for a failure to follow the guidelines appears to be a possible discontinuance of MRC grants.[37] Further, the guidelines do not apply to industry, which means that no matter how well drafted or effective they are within their sphere, as a control on the technology as whole they are inaffective.[38]

Finally, the efficacy of guidelines of any sort has been questioned. Cavalieri warns that guidelines may lull us into a false sense of security[39] and may not be strictly followed, which appears to be the case on at least one documented occasion in the U.S.[40]

In conclusion then, guidelines are seen as a step in the right direction, but they fail to meet all criteria previously outlined. While they are detailed, flexible, and participatory[41], they are not

32. Quoted in (1976), 194 Science 305
33. *Supra* notes 16-18
34. *Supra* note 5
35. Paraphrase of discussion with Dr. W. F. Doolittle, Associate Professor of Biochemistry, Dalhousie University. Dr. Doolittle is himself engaged in Recombinant DNA experimentation.
36. *Supra* note 31, at 47-50
37. *Ibid* at preface.
38. The problem is the same in the U.S., *Supra* note 15, at 231. GMAG is somewhat different in that it applies to British industry, but has no direct statutory force. Rather it survives under the broad umbrella of Health and Safety at Work Act, which lays a duty on all employers and employees to work in the safest way reasonably practical, and provides that failure to do so is a criminal offense. Vickers, *Flexible DNA Regulation: The British Model,* Bulletin of the Atomic Scientists, January 1978, at 4
39. *Supra* note 26
40. *Recombinant DNA: NIH Rules Broken in Insulin Gene Project* (1977), 197 Science 1342
41. For example, the present 10-person MRC Biohazards Committee includes a corporate vice-president, a layman, a cleric, and a law professor.

comprehensive or effective, and it is these missing characteristics which the author considers the most vital.

Legislation

Legislation, in one form or another, is considered the only realistic method of meeting the biohazard presented.[42] While there are numerous forms such legislation could take, a preliminary broad concern, and by no means a simple one, is the questions of constitutional jurisdiction.

Logically, there should one standard (or set of standards) which applies equally and without favour or discrimination to all agencies and experimenters involved in DNA technology. This may indicate a need for federal rather than provincial legislation. However, the subject matter does not fit into any neat categories.[43]

On the provincial side, it can be argued that what is being regulated is a single industry being carried on in the province, and constitutional cases from *Citizens Insurance Co.* v. *Parsons*[44] to the present have consistently upheld the exclusion of federal legislation from this area. In a recent decision dealing with the constitutionality of the federal regulations dealing with the labelling of beer under the *Food and Drugs Act,*[45] the statute and its implementing regulations providing virtually a code governing the manufacture of malt liquor, the Supreme Court reaffirmed that the regulating of the production process of a single industry is *prima facie* a local matter.

On the other hand, there are strong arguments that can be made for federal jurisdiction, especially under the federal residual power for peace, order and good government. In *R.* v. *Houser*[46] the Supreme Court upheld the *Narcotics Control Act* under the federal residual power as legislation adopted to deal with a genuinely new problem which did not exist at the time of confederation, and which went beyond the class of matters of a merely local or private nature. If this argument is valid for narcotics, it is doubly valid for genetic

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42. See M. Mitchell *et al.* Medical Research Council Committee draws up guidelines for research into recombinant DNA (1977), 116 CMA Journal 804
43. In the U.S., for example, the question has not been resolved. In the absence of Federal Legislation, which while in the making, has yet to get off the ground, See Wade, *Congress set to Grapple Again with Gene Splicing* (1978), 199 Science 1319. State and municipal legislatures are enacting regulations. See Wade, *Gene — Splicing: at Grass Roots Level a Hundred Flowers Bloom* (1977), 195 Science 558
44. (1881-83), 7 App. Cas. 96
45. *Labatt's Breweries* v. *Att. Gen. of Canada* (1979), 30 N.R. 496
46. (1979), 46 C.C.C. (2d) 481 (S.C.C.)

engineering. In addition, Estey J. in the *Labatt's* case[47] said:

> . . . Parliament may make laws in relation to health for the peace, order and good government of Canada; quarantine laws come to mind as one example. The Privy Council hinted that legislation enacted by Parliament to deal with an "epidemic of pestilence" would be valid in *Toronto Electric Commissioners* v. *Snider,* [1925] A.C. 396.

This statement would appear to cover exactly the ground with which we are concerned.

The above discussion does not purport to be a definitive exploration of the constitutional question. As originally stated, there is no simple solution. It is suggested, however, that the resolution is, in the final analysis, a question of policy. The courts must place the legislative power where it will be most effective to deal with the foreseen hazard, and to this author at least, that means in the hands of the federal government.

Form of Legislation

Having traversed the constitutional maze, there is still the question of the form the required legislation should take.

On the one hand, one does not want to stifle scientific enthusiasm or development by being too restrictive. On the other hand, having identified a need for some restrictions (whatever they are determined to be), one would like to set up a system in which the consequences of disregarding the restrictions are so prohibitive that such an eventuality is unlikely.

Further, there is the previously discussed desirability of alleviating the rigours of traditional tort law by legislatively dispensing with the concept of negligence in favour of a concept of absolute liability.[48] Finally, one would hope to be able to set up a system such that those involved in the technology police themselves.

These kind of considerations have already been faced in the area of atomic energy, and the legislation enacted to regulate that technology can serve as a model for Biohazard regulation.[49] The *Atomic Energy Control Act*[50] was set up to control and supervise the

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47. *Supra* note 45, at 512
48. *Supra,* at p. 10
49. This is especially true when considering the similarities between the technologies in their novelty, social impact, and potential dangers.
50. R.S.C. 1970, c. A-19

development, application, and use of atomic energy. As a first step, what is envisiged is a "Genetic Engineering Control Act" set along similar lines. Without going into any detail on the specific provisions contents of the act, it should:

(a) apply to the whole field of genetic engineering;

(b) apply to both the public and private sectors, including crown corporations;

(c) be mainly concerned with setting out mandatory guidelines. This could be done through a Board such as the present MRC Biohazards Committee; there could also be provisions for an annual review of the "state of the art" so the guidelines remained flexible; and

(d) provide for fines and/or imprisonment for both the experimenter and the institution within which the experimenter works, for failure to comply with the act or any regulations (the guidelines) made under it.

Secondly, again following the lead of nuclear technology,[51] a "Biological Hazards Liability Act" is needed. This act would:

(a) Impose a duty on both the experimenter and the institution for the genetic engineering being carried on;

(b) provide for absolute liability for injuries;

(c) set out mandatory levels of insurance to be carried;

(d) possibly have some licensing requirement;

(e) set up a committee to handle claims under the act;

It is realized that the acts proposed could well become terribly restrictive. Any licensing requirements for example, could hinder research a great deal if the criteria for granting them became too strenuous. In drafting the legislation therefore, (and in subsequently administering the acts, should they ever be born) what must be kept in mind, is that, rather than trying to restrict the technology, *per se,* the legislation is aimed at laying the responsibility for monitoring the technology in the hands of the practicioners. In short, one aspires toward the optimum system wherein it is in the industry's best interest to regulate itself.

Patentability

Finally, we must look at the products of this technology and provide for them. This is not seen as a separate or alternative solution in the

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51. *Nuclear Liability Act,* R.S.C. 1970 (1st Supp.), c. 29

overall handling of DNA Technology, but rather as simply one more aspect of the total problem which must be addressed in conjunction with all other aspects.

The products of genetic engineering are potentially of immense use to human beings, and consequently in the commercial sense, of potentially immense value. In its *Interferon* cover story, Time Magazine[52] states, "The drug companies know that there is a gold mine in *interferon*. They are scrambling like mad to produce it."

The traditional way of protecting a valued product in industry is through copyright, trade secret or patent. In this context, copyright is not applicable, and the trade secret route is considered inappropriate. The concepts and procedures described herein, of dealing with genetic engineering in any realistic way, would be totally thwarted by industrial secrecy. In fact, the best way of ensuring that industry is not even tempted by the trade secret approach may be to include in the "Genetic Engineering Control Act" described above a provision stipulating that neither the products of genetic engineering nor the direct manufacturing processes are subject to trade secret or trade secret law.

This leaves the question of patentability. Lagging behind the UK by several years, the US Supreme Court has finally resolved the controversy in that country by a 5 to 4 decision in favour of the patentability of living organisms.[53] It is only a matter of time before the question comes before the Canadian Courts.[54]

It is not at all certain that the patentability of living organisms is an issue of major importance in the overall question of genetic engineering, believing as the author does (pessimistically perhaps) that where there is money to be made, industry will involve itself regardless. Further it is not at all certain that patents will be effective to protect the product. Micro organisms are subject to quick and considerable manipulation.[55] Be that as it may, one of the benefits of the patent system, that of "encouraging disclosure to the

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52. *Time*, 31 March 1980, at 47
53. *Supra* note 6
54. There is at present some controversy reported in the media over the patentability of seeds in Canada. This may ultimately spark a confrontation of the issue. See also the representative discussion in Guttag, *The Patentability of Microorganisms* (1977), 13 U. of Richmond Law Rev. 247
55. Dr. S. D. Wainwright, Professor of Biochemistry, of Dalhousie University, is of the opinion that patenting microorgnisms at least, is a lawyers' game only. He feels that once you have a copy of the specially produced organism, it is a simple step to modify it sufficiently to get around the patent laws.

public of mertiorious inventions. . .'',[56] is consistent with the general theme of controlling the whole technology in a meaningful way. If allowing the products of DNA Technology to be patented aids at all in ensuring adherence to the guidelines and safe handling of the technology, the patentability in Canada is a desirable occurrence, (within, of course, the normal patent requirements, of newness, usefullness, etc.). With this in mind, it is probably worth while to bypass the impending legal controversy right now, by amending the present *Patent Act* to clearly allow living organisms to be patented.

IV. *Conclusion*

DNA technology has tremendous potential to ameliorate many human disabilities and should be viewed as a beneficial undertaking. However, there are also potentially serious and far reaching consequences to DNA experiments, and both the industry and the individuals involved in the research must constantly be on guard and cognizant of their duty of care to society.

The present MRC guidelines are an inadequate control on DNA research. Federal legislation is needed to produce nation-wide mandatory guidelines with penalties for non-compliance, and to enact an absolute liability statute that places responsibility for safety directly with the experimenters. Further, the products of DNA experimentation should not be allowed to be the subject to trade secret law, but should be patentable under an amendment to our present *Patent Act*.

It is felt that only a coordinated control system such as herein described will provide the atmosphere of care and diligence needed within the industry and yet not be so restrictive as to stifle research. Above all else, the time for action is now. There is sufficient information available now to lead any rational human being to the conclusion that positive controls are needed. Further delay would not only be unconsciousable; it would be flirting with catastrophe.

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56. Guttag, *supra* note 50, at 277

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