18 The Regulation of Modern Biotechnology: A Historical and European Perspective

A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century

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Introduction

The events described below occurred over a period of two decades, from the mid-1970s, covering the birth and early years of modern biotechnology and the first practical and commercial applications of genetic engineering. The story is a complex one, for the several reasons discussed below: a story of many strands, but also of many interlinkages, many interactions, between the various strands. The danger for any narrator of such a story is that the more comprehensively and thoroughly he presents the complexity, and the mass of detail, the greater is the risk of concealing the salient lessons; and there are important lessons to be learned, by all the different players concerned, but especially for public policy in Europe. Therefore, selectivity, omission and compression have had to be applied, in the interest of greater significance and transparency.

The “story” is about how different societies have coped, are coping, with a sudden surge of knowledge and understanding about the basic structures and mechanisms of living things. In focusing on public policy and regulations, the intention is less to tell the story of the remarkable scientific discoveries and technological developments and inventions, well described elsewhere, than to study how societies learn to digest the new knowledge, and to manage its consequences; in the hope of showing how they may learn faster and manage better.

The various strands of the story are spun and interwoven through time, so time will serve as a common base and organizing principle; although various countries are at different points on their respective “learning curves” of experience, and the curves are not identical.

The learning process which can be perceived across the various strands is a multidimensional one, in several distinct respects:

- multi-disciplinarity of the scientific base
- multi-sectoral applications
- multi-constituency
- multi-national
- multi-international-institutional.

Each of these facets is here briefly introduced, and recurs in the narrative that follows.

The scientific base of biotechnology is multi-disciplinary, drawing upon elements from biochemistry, microbiology, molecular biology, genetics, process engineering (including especially, but not restricted to, fermentation); and no area of the life sciences and technologies has remained unaffected by the surge in knowledge and technique, particularly at the molecular level.

A similar multiplicity characterizes the sectors of application. In every area of human interaction with living entities and systems, there is scope for the application of greater knowledge, and consequently greater subtlety and efficacy of intervention – in agriculture and food production, in health care, and in the recycling of organic wastes, water purification, and protection and management of the natural environment. More “bio-rational” approaches may be seen as good in themselves, for values aesthetic, ecological or economic; or as essential responses to competitive pressures, from competitors to whom the global knowledge base is no less accessible; or as essential tools for maintaining (or achieving) decent standards of health and nutrition, for a human population approaching and passing ten billion, and while reversing the current degradation of the planet.

As issues relating to biotechnology and genetic engineering came into greater prominence, the number of interested “constituencies” increased. The scientists themselves, at Asilomar, initiated through systematic engagement with journalists, a wider debate engaging the political leaders and their staff, and the general public. The previous paragraph refers to the various economic sectors, agricultural, industrial and other, who were progressively drawn into the debate. The circle of debate was further widened by ethical considerations, to draw in philosophers and theologians. Within government, ripples spread from Research Ministries, concerned with both basic and applied science, to applications involving Ministries of Industry and Trade, Agriculture, Health, Environment, Education and others; and issues involving regulatory and legal aspects, engaging Patent
Offices and Ministries of Justice. The sequence in which they awoke or reacted varied from country to country, although within the European Community the processes of Community legislation tended to bring similar Ministries into synchrony in their preoccupations, with biotechnology as with other topics. The debates about biotechnology have from the start been international, because of the natural internationalism of science. As the technologies moved into application, this internationalism was doubly reinforced: by the continuing progress towards an open world economy; and by the increasing significance within that economy of knowledge-intensive sectors (such as biotechnology), and consequently of intellectual property. The former development could be underlined by reference to the 7-year, “Uruguay Round” of GATT negotiations, culminating in the signature of the agreement at Marrakesh in April 1994; the latter aspect, by the significant attention and controversy which biotechnology attracted within the trade-related intellectual property element of the GATT agreement.

The multi-national policy implications and multiplicity of aspects mentioned above had their institutional counterparts, epitomized by the presence of biotechnology on the agenda of practically every agency of the United Nations. UNIDO, UNEP, WHO and FAO collaborated in the development of biotechnology guidelines. Common biotechnology-related policy questions face international agricultural research centers, or international conferences on harmonization of authorization/registration procedures for pharmaceuticals. At the “Earth Summit” in Rio de Janeiro, June 1992, biotechnology figured significantly in the debates on biodiversity, and in the articles of the resulting convention; within the “Agenda 21” development plans for the 21st century, there are many references to biotechnology, including the whole of Chapter 16.

This multidimensional character will be brought out in what follows, drawing particularly on developments within the European Community or Union; whose own constitution and institutional structures were undergoing rapid evolution during the same decades. This aspect interacted significantly, and sometimes adversely, with the process whose description is the central aim of this essay: how societies digest and learn to manage the surge of new knowledge and methods summarized by the word “biotechnology”. Some points are commented on in the narrative; a final section draws together a synthesis and conclusions.

1 Origins and Beginnings: From Avery to Asilomar, and Capitol Hill

1.1 Slow Progress: The Decades Before Asilomar

1994 saw the 50th anniversary of the classic paper by OSWALD AVERY and colleagues (AVERY et al., 1944), in which they identified DNA as the molecule uniquely associated with the storage and transfer of genetic information between different strains of bacteria. His work on *Pneumococcus*, the bacterium responsible for pneumonia, had started three decades earlier during World War I. A decade after AVERY’s paper, WATSON and CRICK used crystallographic data and biochemical reasoning to elucidate the structure of DNA, in the UK MRC’s (Medical Research Council) Laboratory of Molecular Biology, Cambridge. In the same year and laboratory, SANGER published the amino-acid sequence of the protein insulin. X-ray crystallographic methods – developed in Cambridge’s Cavendish Laboratory by the BRAGGS, father and son, in the 1920s – had there first been applied to biological molecules by BERNAL and PERUTZ in the 1930s; an initiative which led, two decades later, to the double helix.

Following the double helix discovery, the genetic code was elucidated; following AVERY, and through the work of LEDERBERG and others, the field of bacterial genetics was progressively developed. But more decades of work and progress elapsed before COHEN
and Boyer at Stanford could (in 1974) publish (and subsequently patent) their use of restriction enzymes with bacterial plasmids for the fundamental “cut and stitch” activities which became known as genetic engineering. Also in the mid-seventies, Sanger, and Gilbert and Maxam at Harvard, published their methods of reading, nucleotide-by-nucleotide, genetic sequences.

This history of some of the most significant discoveries of twentieth-century science has been often and more fully described, for their significance attracts the historians of science, and will long and rightly continue to do so (see, for example, the review by Witkowski, 1988). As background to the policy and regulatory debates which developed around biotechnology, the purpose of recalling the history is to identify the salient factors which lead many observers to speak of the “Genetic Revolution” (e.g., Davis, 1991). A useful chronology of the two latest decades was assembled by Rysser and Weber (1990).

1.2 The Genetic Revolution: Acceleration, and Irreversible Knowledge

As is indicated by the dates quoted, the gestation periods for these major scientific discoveries and developments were measured in decades, rather than years. But from these slow beginnings, a steep acceleration has followed. Understanding of the molecular mechanisms of all living systems was a progressive, interactive process. The interactions stimulated further insights, hypotheses, experiments and discoveries; the process was carried forward in an increasing number of centers around the developed world; the knowledge thus gained was cumulative, irreversible, and globally available. Subversive and pervasive, the discoveries could not be reversed, nor the powerful but simple techniques and methods disintegrated. Could they, should they, be controlled and regulated? That was the original question at Asilomar; and was recurrent through the years that followed.

The subsequent developments in the life sciences and technologies, over the decades from the mid-70s, interacted increasingly with the “Information Revolution” of data storage, software sophistication, computing power, and global electronic networking. By the early ‘90s, DNA sequence data read by automated machinery was pouring into the 2 or 3 global databanks at a rate of millions of nucleotides per month. This flood of new knowledge, of which DNA sequence remains merely one aspect, albeit the most fundamental, has been generated and driven by massive increases in the financial, human and technical resources devoted to the R & D effort, by both governments and private sector. The technical resources themselves have become enormously more efficient and productive, both within the biology laboratory (e.g., in sequencing technology), and in the information handling within and beyond the laboratory: at all levels of scientific data, extending also to clinical, and bibliographic, and beyond science to the provision and use of commercial and legal information, including a related massive growth of patent applications and intellectual property rights.

This quantitative surge of knowledge, and the acceleration of its rate of further expansion, have had, and continue to produce, shock waves: qualitative effects rippling across scientific disciplines, government and international institutions and policies. The shock waves extend through agriculture and food production, health care, and environmental management, reaching into philosophy, theology and ethics. UNESCO in 1993 created an International Committee on Bioethics; over the previous two decades every UN agency had found itself involved in the implications of the new knowledge. An OECD study of long-term economic impacts of biotechnology in the mid-1980s, was obliged to appear with a modified title: “Economic and Wider Impacts of Biotechnology”; for the “Wider” impacts would be noticed first (OECD, 1989).

The changes within the life sciences are profound, as the traditional disciplines are flooded with illumination from the molecular level, from scientists who know not the name of Linnaeus. Virologists who have split over the years into sub-groups focused on bacterial, insect, plant, animal, clinical or other viral
sub-disciplines, now find a re-emergence of common interests, in projects such as the World Virus Databank. Molecular evolution re-examines and illuminates the legacy of Darwin; taxonomy, systematics and nomenclature are reinvigorated and (particularly in the context of declining biodiversity) recognized as essential to the rational structuring and management of the new knowledge.

The implications for public policy of the biological revolution did not strike all departments of government simultaneously, nor similarly. If one uses an orchestral metaphor, the violins of Science had the privilege of initiating the new theme; other sections of government responded as in a fugue, with answers or variations on the theme; and with the increase in the number of sections of government participating, the need for a conductor of the orchestra became ever more apparent. There were to be many orchestras, and many conductors; harmony, and harmonization between traditions and places, proved elusive.

### 1.3 Asilomar

In agricultural or medical research, in plant or animal breeding, and in the production of fermentation antibiotics, the continuing development and application of the life sciences during the early post-war decades were routinely pursued, in familiar compartments with relatively little inter-sectoral interaction, beyond a perfunctory acknowledgement of common roots in biology. Basic science, the dramatic discoveries referred to above, were saluted with Nobel prizes, but impinged only sporadically or slowly on practical concerns. That has changed since the mid-70s.

It has become a convenience or a cliché to date histories of biotechnology from a conference held at Asilomar, California, in February 1975; whose origins were somewhat earlier. In February 1973, a conference on biohazards was held at Asilomar, California. It attracted little attention, but stimulated further thought. In June 1973, the annual session of the Gordon Conference on Nucleic Acids was held in New Hampton, New Hampshire, and was devoted to the problem of hazards in recombinant DNA research. The co-chairs of the conference, Maxine Singer and Dieter Soll, drafted a letter addressed to the National Academy of Sciences and the Institute of Medicine, requesting the formation of a study committee, to assess the biohazards posed by recombinant DNA research, and recommend appropriate action. The letter was published in Science (Singer and Soll, 1973).

As a result, the National Academy of Sciences announced in February 1974, that Paul Berg would chair the study committee. The 11 members, all active in recombinant DNA research, were conscious of the quickening pace of research, and apprehensive about possible accidents. Their report was also published in Science, on 26 July 1974 (Berg et al., 1974), and almost simultaneously (slightly abridged) in Nature. The text of the “Berg letter” is reproduced below:

> “Potential Biohazards of Recombinant DNA Molecules

Recent advances in techniques for the isolation and rejoining of segments of DNA now permit construction of biologically active recombinant DNA molecules in vitro. For example, DNA restriction endonucleases, which generate DNA fragments containing cohesive ends especially suitable for rejoining have been used to create new types of biologically functional bacterial plasmids carrying antibiotic resistance markers and to link Xenopus laevis ribosomal DNA to DNA from a bacterial plasmid. This latter recombinant plasmid has been shown to replicate stably in Escherichia coli where it synthesizes RNA that is complementary to X. laevis ribosomal DNA. Similarly, segments of Drosophila chromosomal DNA have been incorporated into both plasmid and bacteriophage DNAs to yield hybrid molecules that can infect and replicate in E. coli.

Several groups of scientists are now planning to use this technology to create recombinant DNAs from a variety of other viral, animal, and bacterial sources. Although such experiments are likely to facilitate the solution of important theoretical and practical biological problems, they would also result in the creation of novel types of infectious DNA elements whose biological properties cannot be completely predicted in advance.

There is serious concern that some of these artificial recombinant DNA molecules could prove biologically hazardous. One potential hazard in current experiments derives from the need to use a bacterium like E. coli to clone the recombinant
DNA molecules and to amplify their number. Strains of \textit{E. coli} commonly reside in the human intestinal tract, and they are capable of exchanging genetic information with other types of bacteria, some of which are pathogenic to man. Thus, new DNA elements introduced into \textit{E. coli} might possibly become widely disseminated among human, bacterial, plant, or animal populations with unpredictable effects.

Concern for these emerging capabilities was raised by scientists attending the 1973 Gordon Research Conference on Nucleic Acids, who requested that the National Academy of Sciences give consideration to these matters. The undersigned members of a committee, acting on behalf of and with the endorsement of the Assembly of Life Sciences of the National Research Council on this matter, propose the following recommendations.

First, and most important, that until the potential hazards of such recombinant DNA molecules have been better evaluated or until adequate methods are developed for preventing their spread, scientists throughout the world join with the members of this committee in voluntarily deferring the following types of experiments.

\textbf{Type 1:} Construction of new, autonomously replicating bacterial plasmids that might result in the introduction of genetic determinants for antibiotic resistance or bacterial toxin formation into bacterial strains that do not at present carry such determinants; or construction of new bacterial plasmids containing combinations of resistance to clinically useful antibiotics unless plasmids containing such combinations of antibiotic resistance determinants already exist in nature.

\textbf{Type 2:} Linkage of all or segments of the DNAs from oncogenic [cancer-inducing] or other animal viruses to autonomously replicating DNA elements such as bacterial plasmids or other viral DNAs. Such recombinant DNA molecules might be more easily disseminated to bacterial populations in humans and other species, and thus possibly increase the incidence of cancer or other diseases.

Second, plans to link fragments of animal DNAs to bacterial plasmid DNA or bacteriophage DNA should be carefully weighed in light of the fact that many types of animal cell DNAs contain sequences common to RNA tumour viruses. Since joining of any foreign DNA to a DNA replication system creates new recombinant DNA molecules whose biological properties cannot be predicted with certainty, such experiments should not be undertaken lightly.

Third, the director of the National Institutes of Health is requested to give immediate consideration to establishing an advisory committee charged with (i) overseeing an experimental program to evaluate the potential biological and ecological hazards of the above types of recombinant DNA molecules; (ii) developing procedures which will minimize the spread of such molecules within human and other populations; and (iii) devising guidelines to be followed by investigators working with potentially hazardous recombinant DNA molecules.

Fourth, an international meeting of involved scientists from all over the world should be convened early in the coming year to review scientific progress in this area and to further discuss appropriate ways to deal with the potential biohazards of recombinant DNA molecules.

The above recommendations are made with the realization (i) that our concern is based on judgments of potential rather than demonstrated risk since there are few available experimental data on the hazards of such DNA molecules and (ii) that adherence to our major recommendations will entail postponement or possibly abandonment of certain types of scientifically worthwhile experiments. Moreover, we are aware of many theoretical and practical difficulties involved in evaluating the human hazards of such recombinant DNA molecules. Nonetheless, our concern for the possible unfortunate consequences of indiscriminate application of these techniques motivates us to urge all scientists working in this area to join us in agreeing not to initiate experiments of types 1 and 2 above until attempts have been made to evaluate the hazards and some resolution of the outstanding questions has been achieved.

Paul Berg, Chairman
David Baltimore
Herbert W. Boyer
Stanley N. Cohen
Ronald W. Davis
David S. Hogness
Daniel Nathans
Richard Roblin
James D. Watson
Sherman Weissman
Norton D. Zinder
Committee on Recombinant DNA
Molecules Assembly of Life Sciences,
National Research Council,
National Academy of Sciences,
Washington, DC 20418"
At the most factual level, the occasion was an invitation-only scientific meeting in which eminent specialists discussed the possible risks which might be associated with recombinant DNA techniques or experiments; and means for managing or reducing these conjectural risks. There was discussion of various levels of risk for classifying experiments; and corresponding levels of physical containment. Among the more constructive ideas, which British participants such as Brenner emphasized at the conference, was the concept of biological containment: the use of strains of microorganism disabled in ways which would limit their ability to survive or reproduce outside the contained vessel and special conditions provided in the experiment. This area of the Asilomar debate was the starting-point for a great deal of risk assessment research over the following years – practically all of it reassuring, but always limited by the logical impossibility of “proving” a negative.

As an innovation in scientific communication, Asilomar could be seen both at the time and subsequently in various lights. Many commentators are inclined to congratulate the organizers on the integrity and transparency with which they were prepared to communicate their concerns to a broader public. Press representatives were invited to the conference, with the understanding that they would listen to the whole four-day conference before reporting. The resulting reportage was serious and competent, and generally acknowledged the obvious sincerity of the scientists themselves.

Some commentators nonetheless set Asilomar in the context of tradition they would describe as “elitist”, characterized by the arrogant assumption that on complex matters, only those who understand the complexities should be involved in making decisions. Against such elitism it is argued that democratic procedures require the involvement of representatives of a broader constituency – of the taxpayers who have paid for publicly funded research, of the workers who might be the most immediate victims of a laboratory accident or infection, and by the same logic, of the general public who, on various conjectures, might also be victims either of an accident (such as an epidemic initiated by a recombinant organism), or be exposed to risks associated with products placed on the market.

The developments in genetic engineering to which Asilomar drew attention catalyzed a fundamental debate about the control of science and technology; or, insofar as such a debate was already in progress, extended and amplified it to all areas of the life sciences and technologies, their applications, and implications.

1.4 From Asilomar to Capitol Hill: A Dialogue of Scientist, Public and Regulator

The debate triggered by Asilomar was intense and widespread. The temptation to exaggerate and simplify, for journalists, cartoonists, or politicians, local and national, was great; and was not resisted. Scientists were often angered by the misrepresentations, and by the strident and hostile tone of the attacks they encountered – in some notable cases from major environmental movements. But a few eminent scientists supported the critics, in their calls for intense security provisions or a total moratorium on all rDNA research.

The result was a high profile, sometimes heated, public debate, with scientists often facing the ill-informed hostility of “public interest groups” or local politicians. The construction at Harvard University of a high security (“P3”) laboratory for recombinant DNA research led to one such battle, in summer 1976, which was widely reported. This featured the colorful language of the local mayor of Cambridge, Massachusetts, Alfred Velucci:

“It’s about time the scientists began to throw all their god-damned shit right out on the table so that we can discuss it …. Who the hell do the scientists think they are that they can take federal tax dollars that are coming out of our tax returns and do research work that we then cannot come in and question?”

The period of angry debate lasted several years; a period summed up a decade later by Norton Zinder (1986) as “[divisible] into three periods:
Asilomar (1974–76), the ‘recombinant DNA wars’ (1976–78), and detente”.

The American experience during 1974–1978 offered points of comparison for Europe, facing the same issues at approximately the same time; and for both the US and Europe during the second wave of concerns which arose during the latter half of the 1980s. Essentially similar issues were involved in each case.

Public concerns in the United States rose to a peak during 1976–1977, with the corresponding introduction in Congress (both House of Representatives and Senate) of bills to regulate recombinant DNA research. At the same time, following the Asilomar conference, the National Institutes of Health (NIH), under Director DONALD FREDRICKSON, had been active in developing guidelines for the conduct of such research, through the NIH Recombinant DNA Advisory Committee (NIH RAC). The first version of these guidelines was released by NIH on 23 June 1976, and published in the Federal Register on 7 July.

A major feature of the debates in the US was the progressive development of a well-organized, articulate and balanced response by the scientific community. The leading role was played by the American Society of Microbiology (ASM), but many other professional associations of biological and medical sciences joined with ASM in a broad alliance, through semiformal linkages via their executive officers, and widespread networks capable of providing rapid responses.

The recommendations of the ASM were summarized in a nine-point statement, approved in May 1977, and widely reported:

1. That all responsibility for regulating action relative to the production and use of recombinant DNA molecules should be vested in HEW (the Department of Health, Education and Welfare).
2. That to advise and assist the Secretary of HEW, an Advisory Committee should be established whose membership in addition to lay people should include representatives with appropriate technical expertise in this field.
3. That institutions and not individuals should be licensed.
4. That in each institution engaged in DNA recombinant activities, to the maximum extent possible, direct regulatory responsibility should be delegated to a local biohazard committee. These committees should include both members with appropriate expertise conducted at that institution, and representatives of the public.
5. That experiments requiring P1 [the lowest category of physical containment in the NIH RAC guidelines] requirements should be exempt from these regulations.
6. That license removal is an effective and sufficient deterrent to obtain compliance. Further, that ASM is opposed to the bonding of scientists or to the establishing of strict individual liability clauses in the conduct of DNA recombinant activities.
7. That ASM goes on record favoring uniform national standards governing DNA recombinant activities.
8. That the Secretary of HEW should have the flexibility to modify the regulations as further information becomes available. Further, we support the inclusion of a sunset clause in the legislation, i.e., that legislation will be re-evaluated after a fixed period of time.
9. That ASM expresses its concern that in establishing such important legislation governing research, and that this proceed only after due and careful deliberation.” (From HALVORSON, 1986)

The ASM nine points emphasize relevant competence and technical expertise; delegation of responsibility to local committees; applying uniform national standards; the exemption from regulation of low-risk experiments (requiring P1 containment); and flexibility to adapt and re-evaluate legislation in the light of experience. All these points remained valid and important in the discussions during subsequent years and in other countries and legislatures.

During 1977, the scientific concerns were effectively communicated both in public, and to the staff of interested Congressmen. Amendments to earlier bills were prepared, progressively incorporating the scientific advice; informed scientists communicated their personal views on pending legislation to their respective senators or representatives. The information indicating the absence of harmful spread or effects of recombinant organisms was influential. By September, Senator Ad-
LAI STEVENSON wrote (in a letter to the President’s Science Advisor FRANK PRESS) that most of the legislation being considered was ill-designed for achieving its stated objective, namely, protection of the public without impeding research. He indicated his intention to explore the use of existing statutes to regulate recombinant DNA research.

At hearings in November 1977, the ASM expressed their concerns about “the apparent intemperate rush to establish legislation to regulate recombinant research without first consulting with the appropriately qualified scientific and medical experts, the need to understand that early allegations concerning recombinant DNA research were characterized by uncontrolled imagination and excessive claims by individuals who lacked knowledge of infectious disease, and the need for minimal interim legislation to extend appropriate guidelines to all recombinant DNA activities regardless of funding source.”

During the fall of 1977 and in 1978, the ASM continued to work closely with Congressional committees, and the prospect of federal legislation declined.

1.5 Observations

The US experience in the post-Asilomar period was of significance, as a successful example of open dialogue between the scientific and political communities. The successes can be related to the flawless safety record of genetic engineering in the US over the following years; and to the position of scientific and economic leadership in biotechnology which the US maintained. More generally and importantly, the US experience provided, for scientists in all fields and legislatures everywhere, an object lesson in how to manage the interface between science and society in a way that was democratic and transparent; and that in consequence, was generally accepted and effective.

This successful experience was not inevitable. At a national conference in October 1980, on “recombinant DNA and the Federal Government”, presentations were made by Federal officials responsible for agency concerns on the subject (17 Federal agencies participated), by former Congressmen and their key aides responsible for legislative activity in the field, and by Washington lawyers specializing in such issues. Lawyer STEPHAN LAWTON had been involved in drafting one of the main House Bills (for Congressman ROGERS) on regulating DNA research. Having narrated in detail the events during March 1977 to mid-1978, he concludes:

“Here ends the story, but not necessarily the lessons. I believe that all of us can learn from this experience with the recombinant DNA research legislation that did not pass.

Lesson number one is that Congress is very willing and quite able to act very quickly when the public health is at stake.

Lesson number two is that whoever dreamed up the legislative process was a genius to the extent that the legislative process is slow enough to prevent a stampede of unwise legislation.

Lesson number three is that Congress, in my judgement, had and continues to have an extremely healthy opinion of the scientific community. Congress is willing to listen to well-reasoned arguments and, believe it or not, Congressmen have the capacity to change their minds when confronted with new and well-reasoned arguments.”

Presciently, he went on to ask:

“Is the legislation dead? Yes, for the time being. Is it dead forever? Maybe and maybe not. The issue itself will not be dead in Washington for a long time. It will be kept alive for several reasons. First, there are several committees of Congress that continue to hold hearings on the activities of the NIH and on recombinant DNA generally, principally the two science committees which don’t have legislative jurisdiction over the recombinant DNA issues but continue in a very positive way to expose themselves and the public to the issue. Second, there is a very interested, sophisticated medical press in Washington, who will follow the issue. Third, I think the sheer excitement of the issue will keep the question of whether or not there should be governmental involvement with respect to recombinant DNA research alive. These three factors – the science committees’ interest and their oversight hearings, the press, and the sheer excitement of the issues – will keep Congress interested in the issue.”

(LAWTON, 1981)

He concluded with the “old adage in Washington” (of Bismarckian vintage and origin), that “if you want to respect your laws