Regrettably, formal risk--benefit analysis can hardly be applied to recombinant nucleic acid research, for several reasons.

First, the term "recombinant molecule research" covers an extremely broad range of laboratory activities, some of which have already become commonplace in the lab, some of which go on in Nature anyway, some of which are so benign as to be passed over as trivial, some of which are unthinkably hazardous, some of which tax the abilities of accomplished experimentalists, and some of which can easily be done by undergraduates. Generalizing is difficult. It may well prove possible to project the consequences of a particular line of manipulation on a specified strain; but efforts to make generic decisions by examining the experiments on a category-by-category basis may blur certain key distinctions.

Second, the long-term consequences of the various imaginable experiments are not at all well understood. There have already been surprises. This research tinkers with the very essence of life-forms. Although we are now beginning to acquire an understanding of these transmutations, few researchers claim

situation being analyzed: that is, if this variable is increased or that one clamped down on, the outcome changes. But such is not neatly the case here. Both the overall schemes and the detailed techniques of DNA research are now widely disseminated. The experiments are intellectually intriguing and have been touted to hold practical promise. Even if the United States by some heavy-handed action censured all such work and prohibited recombinant research within its borders, I doubt that the research would be brought to an end everywhere.

Thus, although I believe that the various exercises referred to as "risk--benefit analysis" can be illuminating on activities having defineable, predictable outcomes under control by public decisionmakers, I do not believe that the bulk of the DNA experimentation issues are amenable to such analysis. They may be someday, but they are not now.

So what approach should we take? I have to start from the premises that a wide range of experiments is possible and will be extremely tempting to continue, not only here but elsewhere; that external guidance upon the research community is legitimate but must be exerted judiciously; and that opportunities for bettering our worldly condition should not be passed up lightly.

their pathogenicity. Analysis of these effects extends far beyond the range of molecular genetics and involves many disciplines.

I see this nucleic acid research not as a defined system amenable to analysis in the way that a transportation network or a well-charted mine might be, but as an exploration of open and uncharted territory with unknown passages, speculative but uncharted riches, and speculative but uncharted hazards -- territory through which some are already proceeding and will no doubt bring back both hitherto unknown riches and unknown scourges.

For such a territory, formal analysis may not help as much as appraising the problems case-by-case and issue-by-issue; devoting proper attention to the baseline experiments; pacing the research so that no matter what the outcomes the public has time and opportunity to inquire, adjust, and express its preferences; carrying the issue into international forums; and building in professional and institutional mechanisms of ongoing review.

I will always concede that is a good way to do business—if you can put numbers on all of these branches. That leads to another realm of discussion.

Mr. THORNTON. Yes.

Dr. LOWRANCE. Recombinant DNA research has several features that viewed together make it a novel case. There are obvious genetic changes, largely irreversible, passed on to succeeding generations. With the test organisms that survive outside the laboratory these effects may be transmitted widely and involuntarily upon the larger public. The very process of gathering experimental information required to make a full appraisal of the situation may in itself bring hazard. We don't know the problems of the experiments until we do the experiments.

I would say formal risk-benefit analysis finds its best application in policy situations in which the elements of the analysis are somehow parallel to the elements under examination in the real world, feeling that if you cut back on this variable or increase that one in your analysis you can imagine the real world changing in the same direction.

It seems to me that since in a sense the horse is out of the barn, or the cat is out of the bag, in this case, we may not have perfect control over the real-world situation. Although we might make an appraisal that says we should cut back on this research somehow, I am not sure we would be able to stop it in the whole world.

My point in the prepared testimony was that even if the United States in some heavy-handed action censured all work in the world, and absolutely prohibited recombinant DNA research within its borders, I doubt that research would be brought to an end everywhere else.

So one of my concerns is that we set the right precedent, seize this opportunity for responsibility, and set baselines.

In summary, I think formal risk-benefit analysis for the moment just fails us with the DNA research. Perhaps 10 years or 20 years from now we can do formal analysis. For the moment, I think we need a much more flexible approach involving a wide range of people, not just molecular geneticists but also those concerned with the problems of survivability of these test organisms outside the laboratory, some of the problems of immunology, fine distinctions among subspecies, and so on.

In conclusion, I see this nucleic acid research not as a defined system amenable to analysis in the way a transportation network or well-charted mine might be, but exploration of open and uncharted territory with speculative but uncharted riches and speculative but uncharted hazards. Some are proceeding through that territory already. We don't know what they will bring back: some of the riches, and, perhaps, some of the scourges.

My approach would be to encourage society to undertake voluntary restraint and set up mechanisms of scientific institutional review. I think the research community has shown in its first few years of examination a willingness to bring in people from outside the scientific community, and a willingness to talk to ethicists, with lawyers, with people from the churches, and with all the various public leaders. I think that should be encouraged.

how. It is coming in from outer space, or up from the rocks of the Earth, and so on.

In most areas of serious hazard there is some natural background. One has to think of that as one goes along.

Mr. THORNTON. Thank you very much.

Dr. Michael, I am looking forward to your presentation. It is also a very thoughtful and careful characterization of the problems inherent in the area of determining risk-benefit analysis.

I want to ask you first if you would like to have your paper made part of the report verbatim.

Dr. MICHAEL. I would appreciate that.

Mr. THORNTON. Without objection that will be done.

I ask you to proceed.

Dr. MICHAEL. Thank you, Mr. Chairman.

[The biographical sketch and complete statement of Dr. Michael follows:]

DONALD N. MICHAEL

Dr. Donald N. Michael was born in Chicago in 1923. He is a social psychologist with a background in the physical sciences, and was educated at Harvard and the University of Chicago. Throughout his professional career he has combined his interest in the physical and the social sciences. After receiving his Ph. D. from Harvard he taught at Boston University and did research on teaching from audiovisual aids. In 1953 he joined the Weapons Systems Evaluation Group of the Joint Chiefs of Staff as Staff Social Scientist. One year later he became Advisor on Attitude Research on National Science Policy for the National Science Foundation. From 1956 to 1959 he was Senior Research Associate with the research firm of Dunlap and Associates, Inc., Stamford, Conn., where he did extensive work on civil defense problems. From 1959 to 1961 he was senior staff member of the Brookings Institution in Washington, D.C. There he directed a study for the National Aeronautics and Space Administration on the social implications of peaceful space activities. Subsequently, he was Director of the Peace Research Institute in Washington, D.C.; later a Resident Fellow of the Institute for Policy Studies there. Presently he is Professor of Psychology, Professor of Planning and Public Policy, and a Program Director in the Center for Research on Utilization of Scientific Knowledge, Institute for Social Research, at the University of Michigan, Ann Arbor, Michigan.

Dr. Michael has been a consultant to UNESCO and the Committee on Disaster Studies of the National Research Council. He was chairman of the Committee on Psychological Problems of Long-Range Planning of the Society for the Psychological Study of Social Issues, and a member of the ad hoc Committee on Youth Services, Childrens Bureau of the Department of Health, Education, and Welfare. He was a member of the Commission to Study the Organization of Peace and of two of the task forces of the Commission on the Year 2000. He is a member of the Club of Rome.

He has published many professional papers, essays, and reports on practical and theoretical problems having to do with man's ability to adjust to the social and psychological changes which rapidly changing technology produces. Among these are the Brookings Institution publication, "Proposed Studies on the Implications of Peaceful Space Activities for Human Affairs," and "Cybernation: the Silent Conquest," published by the fund for the Republic's Center for the Study of Democratic Institutions at Santa Barbara. His book, "The Next Generation: Prospects Ahead for the Youth of Today and Tomorrow," was published in 1965 and also published in a French translation. "The Unprepared Society: Planning for a Precarious Future," was published in 1968 and later in Swedish and Korean translations. His most recent book, published in 1973, is "On Learning to Plan—and Planning to Learn: The Social Psychology of Changing Toward Future-Responsive Societal Learning."

He is a Fellow of the American Association for the Advancement of Science, the American Psychological Association, and the Society for the Psychological Study of Social Issues. He has been a member of the Federation of American Scientists, the Cosmos Club, the New York Academy of Sciences, and the Society of Sigma Xi.

R/B analysis engenders among its users a pseudo-reality which encourages and sustains the belief that what has been measured has been done so with precision and discrimination both as to concept and content. It also encourages an acceptance that the world can be clearly and correctly represented by such numbers. Moreover, the use of such indices, correlations, etc. depend on aggregating vast amounts of information. Such aggregated representations of reality, by the very grip on complexity they seem to provide, discourage keeping in mind the fact and flux of complexity.

Caveats not withstanding, R/B analysis encourages discussion as if all aspects had been considered, as if the analysis dealt with everything relevant. Of particular importance the calculation of probabilities makes it seem as if all contingencies had been anticipated including the unlikely ones. What can't be included however, are the unthought of eventualities that always arise in complex real life.

The dependence on data and numbers conveys an unmerited value-free, objective image of R/B measures. But any calculations accomplished with limited time, money, and management competence means that trade offs and compromises must be made regarding what issues are deemed important, what time perspectives will bound the study, what data can be collected, what disciplines and methods are presumed useful, and what conclusions will be credible to the sponsor. The study then is never the whole picture because within its own terms not everything can be done and because any study that must restrict itself to quantitative analysis cannot deal with much of what comprise the risks and benefits to humans--the flux of values, norms, aesthetic, spiritual, and such considerations that give direction and meaning to those activities that we can measure and describe with numbers. Indeed the very question of what constitutes a risk or benefit should depend on the characteristics of persons or groups and not on the particular beliefs or preferences of those doing the analysis. But not all that is important for those at risk or benefit is expressible by them. The methods available to learn what they hope and fear cannot always elicit that information. And some crucially important feelings and understandings just can't be put in words. And even if the information were available, time and money may preclude acquiring and using it.[1]

These limitations along with the earlier described societal context, can enhance the special usefulness of risk benefit analysis.

By the very attention the analysis must bestow on the interactive aspects of the issue R/B helps emphasize the systemic nature of the issue and whatever means are contrived for dealing with it.

By its efforts to define carefully and gather data, in order to clarify anticedent and consequent aspects of the issue, R/B analysis helps legitimate a norm for stakeholders to interpret and reason carefully and deliberately. The methods need not preclude passion from the subsequent dialogue about the sufficiency and implications of the analysis but they do encourage on the participants to advance passionately held concerns through careful reasoning.[2]

Risk calculation in the case of recombinant DNA is comparatively more problematic because of the potential for world-wide consequences. This means that less than a world-wide process of decision making and regulation is at the wrong scale to give reasonable assurances that risks calculated on the basis of a local or national set of control assumptions will be an adequate basis against which to balance off the hoped for benefits.

Lastly, benefits will depend on what future societies will need and want. Ours and indeed the world is in a turbulent process of radically re-evaluating and transforming needs and wants and the very criteria for assessing and attaining them. This turbulent process is hardly understood; hence no adequate models exist for representing it much less on which to base calculations relevant for the actual victims or beneficiaries.

Where does this leave us? All too briefly and with due respect for your prior appreciation of the situation, I propose the following. Use R/B to sharpen the issues: both those dealt with and those that need to be but aren't. Treat all R/B analyses as subtly and importantly value biased. Therefore insist on multiple assessments. Encourage multiple participation in evaluation of the assessments. Recognize that we face a profound necessity to invent new ways to decide these issues that transcend in their ethics and potential impact the norms and procedures that we bring from a less complex, less closely-coupled, less participative world. Recognize too that we need to invent new ways and norms for deciding who decides who decides these things.[5] Above all, recognize that we will have to learn what to do and how to do it. We must become a learning society that knows it doesn't know and that knows, too, that all its institutions, norms, and values will need to be reassessed for the risks and benefits attached to holding to them or transforming them.[6]

Who Decides Who Decides:
Some Dilemmas and Other Hopes

by

Donald N. Michael

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In this chapter I shall use the question of who should decide whether to undertake recombinant DNA research in a publicly supported university to illuminate some aspects of the increasingly pressing problem facing this society: what persons and procedures should determine whether to undertake publicly supported esoteric science that is potentially hazardous? The recombinant DNA issue is a prototype of things to come, especially in research conducted in the biological and possibly in the social sciences. The University of Michigan, as a publicly supported institution has an obligation to serve the public interest: it is a prime example of that large variety of organizations whose very existance depends on direct or indirect support from funds produced through taxes. Hopefully, we can understand better the nature of the general problem we face by relating its abstract aspects to a real-life example. This I shall try to do by alternating between abstract exploration of the problem and attention to aspects of the University of Michigan experience that give substance to it.[1]

A conventional response to the questions raised at the beginning of this chapter would be that the decision, being based on esoteric knowledge and intentions and being undertaken at least in part for the public good, should be decided by scientists involved and by the relevant administrators (in this case, those of the University), probably with occasions provided for comment and suggestion from the community at large. But when all is said and done the decision should be made by the conventional decision making structure which, it is presumed, has the best interests of all parties at heart. This is especially so in cases of scientific research because disinterested good will can be expected to prevail and new knowledge can

of research substances into the environment outside the laboratory. Product risks pertain to the consequences of deliberate dissemination into the environment beyond the laboratory of the products finally produced from the research effort. The arguments for and against recombinant DNA research revolve around both of these risks. In the case of product risks the arguments have to do with whether the hoped for but undemonstrated benefits of such research will outweigh the feared and unknown costs. The costs are unknown in part because of our ignorance concerning interactions of these new,"chimeric," life forms and natural life forms and in part because such research carries the potential for irreversibly changing human life itself.[2] This enormously complex issue generates problems that go far beyond the costs and benefits of more conventional technologies, but it is not the topic of this chapter except to observe that beliefs about the long run balance of product costs and benefits probably influence feelings about the degree to which process risks should be accepted in the short run.

Arguments about process risks have to do with how perfectly the laboratories and their biological contents can, in practice, be insulated from the community which surrounds them and whether, if such substances were leaked into the larger environment, they could be expected to have deleterious impacts. The esoteric issues of biology and of probability calculations involved in such an assessment are not the topic of this chapter, either, beyond observing that it is generally conceeded that: (1) extant probability calculations assume ideal performances by all researchers and other professional and nonprofessional staff associated

on expertise and duly constituted authority, and of the conventional overriding priority assigned to freedom of inquiry. The four sources examined here are not the only ones but they especially well illustrate the extraordinariness and the complexity of the decision making task with which scientific endeavors like recombinant DNA research now burden our changing society.

In the first place there is growing subscription to the ideological and psychological virtues of direct or at least less indirect citizen participation in decision making. The ideological argument asserts that such participation is a right of any person or group that might suffer the consequences of unilateral decisions made by a formal organization. Psychologically, it is argued that decisions can be improved and consensus and a sense of community enhanced if the recipient publics participate in the formulation of the questions and the design of solutions to them. In this way both the problem and the solution become "theirs": They understand the tasks and problems involved in defining and implementing the decision and thereby they experience a deeper sense of responsibility toward and commitment to the decision. In addition, and of central importance here, participation provides the occasion for recognizing, for discovering, ethical issues. By itself participation does not resolve them. But it does provide the occasion for creating, for learning new ethical norms. And the situation we face is in every respect one we shall have to learn about and learn what to do about--as I shall emphasize throughout this chapter.

A second source of pressure for new decision making practices is a growing challenge to the autonomy generally accorded to scientific

vested mutual interests--interests reflected in decisions which often are not the same as those which would seem right to the publics who pay the bills and sustain the risks.

The fourth factor that exacerbates all the others and especially challenges conventional authority and decision making processes, is widening recognition that science is not ethically neutral and, thereby, that decisions regarding science and technology cannot be made exclusively in terms of scientific and technical arguments even though these must be critical contributions to the decisions.[6] Inevitably, the scientific and technical facts and data are incomplete, especially in new areas (such as recombinant DNA research). What is more, the available facts and data result from earlier decisions about what merited most attention and what could be learned with available time and money. As such, the available facts and data are expressions of the value judgments (or biases) of those who collected and those who funded the collection of the data. Such judgments necessarily go beyond purely logical, technical, issues into realms of political feasibility, esthetic norms, rightness, and goodness.

All of these considerations were part of the local and national dialogue which informed the University of Michigan experience. My informal canvasing of the motives and expectations of those more or less directly involved indicated that the Forums, the most explicit and dramatic invitation for the University and Ann Arbor community engagement, were seen as variously as: mere ritual; or building a new consciousness about the relationship of publicly supported institutional research and the surrounding community; or as a "laboratory" for developing new means for university-community decision making. Only a minority argued that Ann Arbor

From this perspective, if the University were to forefit, through citizen involvement, its exclusive right (within NIH regulations) to determine whether recombinant DNA research should be undertaken, it would very likely be establishing a precedent not only with regard to freedom of inquiry in this area but in any other area of the natural or social sciences where members of the community could argue that they were being put at physical or emotional risk by the research process itself or its possible products. Given changes in attitudes toward science, participation, and decision making, reviewed earlier, such a precedent would profoundly disrupt the elaborate and subtle mechanisms that motivate and guide science and systematic inquiry in general. Consequences would be as unpredictable and possibly as societally catastrophic as those feared from the DNA research itself. However, some would argue (myself included) that the very fact of growing challenges to the ethic of freedom of inquiry and to its maintenance through "duly constituted authority," make it all the more necessary to begin now to discover new ways that might reconcile the demands for participation by those putatively at risk with demands for protection of freedom of inquiry. Both demands carry very heavy costs as well as very great benefits: it is the recognition of these and the need, therefore, for a new overarching ethic that endowed the recombinant DNA research decision making issue with both symbolic potency and unique potential for initiating learning about what such an ethic might be and how it might express itself in decision making about such activities. It is going to take time and much experience to learn what values and techniques work and the hour is already late. What then

the constraints were too stringent some scientists would disregard them.[10] But the fundamental flaw in the NIH approach was that it reinforced the usual mode of operation wherein geographically separate institutions compete for funds and for the prestige won through successful research. This mode inevitably puts a premium on getting their "first with the most," and it focuses concern at the local level over whether to incur the associated risks.[11] (Even though a local accident might result in world wide consequences, the "acceptability" of the risk probably depends on one's perceived geographic proximity to the source.) At the same time and place, those seeking to do the research are acutely motivated by recognition that they are in competition with scientists in other locales who may not be delayed by local demands for community involvement. Therefore, localization of risk, on the one hand, and pressures to get on with the research, on the other, can be expected to be a likely setting in which new forms of decision making will need to be created and implemented. That context is assumed in what follows.

Under these circumstances who, then, should be involved in decision making? How are they to be involved? And how are they to become involved? Criteria for choosing revolve around questions of 1) the "right" to involvement by virtue of some special capabilities or competences; and 2) expediency, i.e., the consequences of recognizing or ignoring claims. Here, one's role and expectancies about self and others, engendered and sutained by that role, critically influence the preferences and prejudices one brings to this task of choosing who should participate.

in the community? Members of the Community Council? The Mayor? The leaders of the various socially active religious groups? Unofficial but influential groups like the Ann Arbor Citizens Council or the League of Women Voters? Different groups will themselves have differing views as to what constitutes competence and appropriate responsibility for participation.

Finally, there are the competences needed to represent future generations. How are these to be defined and who is to judge?

A second general category of claims on participation in decision making pertains to "turf" protection. Whether or not the research is done will affect the status of persons, the dominance disciplines, the comparative power of administrators, research directors, deans, and so on. For example, in the University of Michigan case, in many eyes important contributions to the University's prestige and, therefore, to its future overall research budget (its "turf" vis-a-vis other universities) would depend on vigorous involvement in recombinant DNA research. (Others argued that the University would gain prestige by leading the way in rejecting the research.) If the community were to be involved in the decisions analogous concerns with "turf" protection would arise there too.

Related claims on participation would be in terms of risk to personal reputation and income (including consulting fees) if the research were not done and from physical exposure to these synthetic biological entities if it were done. And if accidental leaks from the laboratory cause damage, who would be at risk financially if the University is sued by all those allegedly harmed?

decision making network who claim a right to participate in the decisions do so on the basis of values and norms not necessarily compatable with those characterizing the conventional system. So, the almost unnoticed steps, or at least comparatively routine steps, taken in a conventional decision making system now become serious questions of procedures and tactics. Getting from "here to there" will require new social inventions and probably new norms to legitimate those inventions. These, then, seem to be steps necessary to set in motion a process pre-requisite for inventing new decision processes.

Step 1: The community must organize itself to make its claim for participation. Not only is there the task of generating and focusing community interest, but the question must be answered, "Who constitutes 'community'?" Crudely, how many people in the community, or which groups in the community need to be engaged for them a) to claim successfully to represent the community interest in whether research should be undertaken, and b) for the organization doing the research to accept them as representing that interest? Putting it another way, is it possible to deal with this situation through some institutionalized community process rather than the make-shift approaches that would tend to be used if the community were to hostily confront the institution?[13] Can we reach out tentatively with the intention of learning how to do these things deliberately and in good spirits instead of waiting until anger, confusion, and multiple extraneous interests collude to force a messy and uninformative confrontation?

Step 2: Assume that, one way or another, the community has created some kind of representative entity to engage the organization in discussion

At the University of Michigan, individuals, ad hoc groups, (especially the one formed around Professor Susan Wright's memoranda to Committee B), and the University Values Program, all espousing the need to face the question of community participation, but not representing Ann Arbor as such, sought out members of the Board of Regents, the Vice President for Research, members of Committees B and A, the Senate Assembly and the Senate Advisory Committee on University Affairs (SACUA). The result was University-wide moral and financial support for the Forums (including invitations to outside experts to participate). The Forums and further conversations and memoranda also contributed to the extraordinary attention the Regents devoted to the issue.

These activities were influenced by some in the University who put much effort into alerting others in and out of the University to the need for a public airing.[14] Their varying interpretations of the situation converged in a belief that these activities offered a real potential for new processes of University-community interaction. But how all this might have gone if it had been evident that the Ann Arbor community was going to insist on an active role in the initial decision is problematic. That never happened nor was it expected to at the time when various groups in the University agreed to support the Forums. However, it may well be that some justified complacency allowed this institution to be more innovative than it would have been if the community had been more assertive. Thus the absence of crisis also made it possible to draw many in the University into the issue in ways that resulted in learning which might be useful in less tranquil circumstances should they eventuate.

Though highly unlikely, under other more intense circumstances, even though the University might steadfastly protest interference with freedom of inquiry, the Regents or judicial authority might conceivably require the University to include Ann Arbor citizens in the decision making and also specify the criteria for selection as well as the decision making procedures.

There is a less precipitous approach to new answers to the Step 3 question: collaboration and inventiveness depend on the extent to which trust can be built up between the interested parties and, through trust, appropriate norms evolved. Denial of organizational legitimacy and insistence on fuller participation are in part the result of acute distrust of the conventional decision making processes in organizations. Trust and shared norms probably can only be re-established under circumstances which encourage and reward experiments with--and acknowledgment of the need for--new decision making methods and norms explicitly designed to make decisions about who is to make risk-relevant decisions. The shared experience of learning together how to do these things seem prerequisite for creating decision process norms commensurate with the enormity of decisions affecting the impact of esoteric and powerful science on an increasingly complex and vulnerable world.

Assume that a decision is made to involve citizens in subsequent decisions. Step 4, then, attends to the question: How could the decision-making process be operated so that the citizen members can have a truly potent role in influencing outcomes? It has taken many years to invent and refine decision making processes in more conventional areas of an open society and the same can be expected here. There is no reason to expect

will make the decisions facilitated by these procedures. However, explicit intentions to experiment with such procedures as these might simplify somewhat questions regarding appropriate competences and the focus of the decision making task. At least such intentions could color expectations about what is to be done and how and this, in turn, could contribute to the building of trust and shared norms.

Community members may well find themselves in a minority status in the decision making entity if their role leads them to a different perspective from those representing organizational and scientific interests. Then they may be a minority in numbers as well as in their position on the issue. Sometimes other members of the deciding entity may find themselves in the minority. Either way, but especially because of the potentiality of different interests of the community members, minority positions must be able to have access to special resources 1) in order that they may make the best case they can as they develop their position(s); and 2) so that they can disseminate it to potentially supportive constituencies in and outside the organization proposing the research. These resources will be especially necessary if a "minority" position is being espoused regarding an upcoming decision choice. And, in the very nature of the issues, perspectives that lead to rejecting or questioning the conventional wisdom of the "experts" about the costs and benefits of proposed research or the appropriate context for evaluating them are likely to be minority positions. Yet in novel and momentus areas as those involving powerful new scientific knowledge and technique the minority position may well be precisely the one that most merits intensive and early amplification and attention if wise decisions are to be made later.

where we think we want to go; if we are getting there; and if we still want to. Rapidly changing circumstances permit no other mode of rational conduct.

Making decisions in areas of changing values, risks, and ambiguities require profound perhaps radical changes in the norms by which decision-making entities in research oriented organizations operate and in the ends for which they operate. In essence, these entities also have to learn how to design themselves so that they are effective learning systems to the end of improving the effectiveness of community and organization participation in decisions about esoteric scientific activities that involve potential community risks as well as potential benefits.

More specifically, this requires of decision making entities, seeking to learn their way through newly emerging issues wherein the public interest seems to confront freedom of inquiry:

(1) a shared learning relationship instead of an adversarial stance. A zero-sum approach, an assumption that there is one right answer and that only one side can win, can only lead to disaster;

(2) an openness to continuous re-examination of the norms and values by which they operate and for which they operate. It will be especially necessary to re-examine continuously the means for estimating and evaluating social costs and benefits. Alternate scenarios will need to be explicated so that the community and the research organization will have the broadest possible perspective for decision making in these ambiguous and ambivalent areas; and

FOOTNOTES

1. It is right that at the outset I give my personal position on the topic of this chapter. In November of 1975, Professor Susan Wright shared with me and a few others a memorandum she was addressing to Committee B requesting more attention to certain aspects of the risks associated with recombinant DNA research. (Until then I was unaware of Committee B or of the question of recombinant DNA research at the University of Michigan.) I immediately became involved in efforts to bring the community into the picture through participation in a small ad hoc group inspired by Professor Wright's concerns; as a member of the group guiding the University Values Program, and, later, as a member of the committee designated to plan the Forums.

I became involved because of my concern with the issue per se and because the recombinant DNA research issue was an invaluable occasion for the University and the community to begin to learn how to deal with such issues. My personal, cautious, inclination is toward community involvement in the basic decisions. Cautious, because I also acknowledge the dilemmas and difficulties described in this chapter.

It remains for me to acknowledge that we who ponder on and seek to act regarding the place of science in society are caught in a maze of distorting mirrors that reflect the currents and conflicts in our culture and its many sub-cultures and, therefore, in ourselves. We too are mirrors caught up in the maze and contributing to the maze. No matter how much we act with good will and seek to be unbiased we are, ineluctably, mirrors.

2. See Leon R. Kass. "The new biology: What price relieving man's estate?" Science, November 19, 1971, 174, 779-788.

3. "Environmental science, today, is unable to match the needs of society for definitive information, predictive capability, and the analysis of environmental systems as systems. Because existing data and current theoretical models are inadequate, environmental science remains unable in virtually all areas of application to offer more than qualitative interpretations or suggestions of environmental change that may occur in response to specific actions." National Science Board/National Science Foundation. Environmental Science, 1971, p. viii.

4. Recall that two large commercial aircraft collided over the Grand Canyon. An Air Force bomber hit the top floors of the Empire State Building. The ocean liner, Andrea Doria, sank after a collision with another ocean liner in clear, calm weather in mid-ocean. The oil tanker, Torrey Canyon, went aground on well-known shoals spilling oil all over the Southeast English coast. Three astronauts burned to death in a routine test on the launching pad. The unsinkable Titanic sank on its maiden voyage.

13. A dilemma: How to make the community aware that there is a risk and that the consequences may be grave indeed without inflating the issue to panic proportions. Panic would obviate deliberate and enlightened decision making and also destroy chances for emergence of an attitude which would make the eventual decision at least tolerable to most if not all parties. While not precisely this situation, Cambridge, Massachusetts' response to Harvard's research intentions is most informative. See Recombinant DNA: Cambridge City Council votes moratorium. Science, July 23, 1976, 193, 300-301.

A related difficulty merits comment. If the research organization is a university the chances are (as in the University of Michigan case and at Harvard) that some community interest will be stimulated by University personnel. While it needn't work this way, it is likely that signals of concern, especially the early ones will be carried from the University to the community by University people. If community interest grows and if that interest is antagonistic to the conduct of the proposed research, the risk of polarization within the University itself will also grow. Polarization would destroy the openness necessary among University members if there is to be social learning and invention of the high order that will be required to cope with such problems.

14. Committee B had been open to input from the community but until the aforementioned groups became active some two months before the Forums, chiefly as a result of Professor Susan Wright's memoranda to Committee B, there had been little public or University-wide attention to the matter.

15. Roland Warren. Love, truth, and social change. Chicago: Rand McNally, 1971, p. 298.

16. See Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology. The science court experiment: An interim report. Science, August 20, 1976, 193, 653-656; and P. M. Boffey. Science court: High officials back test of controversial concept. Science, October 8, 1976, 194, 167-169.

17. See R. L. Wolf, J. Potter, & B. Baxter. The judicial approach to educational evaluation. April 1976. A transcript of an instructional tape on the Judicial Evaluation Model. The tape was presented at the Annual Meeting of the American Educational Research Association, San Francisco, April 1976. Information about this tape can be obtained from Dr. Robert L. Wolf, Education 325, Indiana University, Bloomington, Indiana 47401.

18. See K. R. Hammond, & L. Adelman. Science, values and human judgment. Science, October 22, 1976, 194, 389-396.

19. For a most perceptive critique of the "devil's advocate" role and its limits see, A. Hirschman. Exit, voice and loyalty. Cambridge, Mass: Harvard University Press, 1970.

introducing it into the environment does not of itself in any sense guarantee that the impact will damp out at some point. By then the ecosystem may have been irreversibly damaged, as we can see in such examples as the deserts in the northern Sahara and in our southwest, both of which were at least in part consequences of irreversible interventions by humans.

This question of irreversibility becomes extraordinarily important in this recombinant DNA case, because we tend to think that if we knew its characteristics we would be able to predict its effects on the environment. The fact is, we simply do not know enough about the dynamics of complex natural environments, either in theory or through data, to understand what the consequences would be of the intrusion of these chimeric life forms. It is a theory—it is not clear it is true—that occasionally there are such "spliced" exchanges of DNA naturally. Even assuming that theory is true, they have been at a rate and under circumstances which so far have been absorbable by the ecosystem—though we would not know what changes in the rest of the system were produced in the process. There is no reason to suppose human interventions of a quite different order of frequency and artificiality might leave things as stable as they are now.

So the fact is, we simply do not understand our ecosystem well enough to make risks analyses with any assurety based on what we think we understand about the characteristics of one or another chimeric entity.

Another type of risk which is extremely uncomfortable to mention and which tends to be avoided, in my experience discussing these matters, is the risk of human failure. We set high standards for laboratory security and for the design of experiments. (That is, we set them as high as the definition of safety needs and the willingness of the research community to go along with these definition allows). However calculations based on these standards do not acknowledge that people make mistakes. They make mistakes either out of simple carelessness or oversight or because they are emotionally disturbed at the time or persistently.

As I indicate in my written testimony, there is no reason to suppose scientists, students, or the custodial personnel will remain free of momentary or persistant mental disabilities which could reflect themselves in lapses in conduct that might allow the escape of these chimeric entities.

So we have no way of calculating the likelihood or interactiveness of these human errors. But we can be sure accidents will happen. All kinds of unexpected, extremely unlikely accidents have happened. In my written testimony I singled out, a recent highly unlikely accident: the Tenerife Airport disaster which was the result of human error involving highly qualified personnel and which happened in spite of very well-developed regulations evolved over the years, as a result, in part, of learning from other accidents.

There is no reason to suppose the situation will be different with DNA, and there is no way to calculate that risk.

Two other aspects I want to mention: One, which Dr. Lowrance referred to already, is the peculiar situation with regard to the risks and benefits of recombinant DNA, certainly the risks, that the dangers could be on a worldwide scale. Yet the very means we now have for

kinds of explorations, require that we re-examine all our values and operating premises, not just some of them. And this brings me around again to the question of the relation between the public interest and freedom to do research that might be risky; to freedom of inquiry.

Just as we have to reassess how we are going to allocate risks and benefits, and who is to make those allocations, I think we have to reassess as well such fundamental premises such as the right to unlimited freedom of inquiry. Maybe we have reached a time, I don't know, but maybe we have reached a time where, just as much as we must reexamine the human condition regarding gains and losses from things like recombinant DNA research, we have to reexamine the human condition regarding gains and losses from controlling freedom of inquiry.

I don't think this issue is any more exempt from reexamination than the rest of the value premises involved in judging risks and benefits.

Mr. THORNTON. Thank you very much, Dr. Michael, for a very fine summary and amplification of your prepared statement.

Indeed, I think that you have centered upon the crucial issue which is involved in these hearings, it is not merely the question of what we do with this particular problem of recombinant DNA research.

Mr. THORNTON. An important issue is: What do we do about the dilemma which is posed by man's curiosity constantly driving him to explore the unknown.

I think it is correct that one should prod the unknown with a great deal of care because of the risk that it may prod you back.

At the same time, to alter man's character so as to make him accept ignorance rather than take the risk of learning may also be an irreversible force for man and for the future of our world.

Dr. MICHAEL. Yes, I thoroughly share that concern. If I may, I would like to add a couple comments.

(1) We should recognize that the emphasis we put on freedom of inquiry and searching after new knowledge, is a particular strength of Western society over the last 300 years, that grew out of the Age of Enlightenment. There are many, many societies in the world, probably most of them, where the desire, the motive, to explore the unknown is not nearly as intense and is much more channeled than it is in Western society. And it does not follow that those people are less full human beings or less happy. They may not be as well medicated or warmed in the winter and cooled in the summer, but, as you know, the value of such benefits are subject to reexamination now by more and more people in our society.

Secondly, the fact is that we do constrain inquiry. Our myth is that we don't. But as you know, there was congressional action to prohibit a certain research project to be undertaken at the University of Indiana connecting marijuana and sexual desire. It has been very hard to do any research concerning drugs such as LSD, and so on.

So it is not true we do not restrict inquiry. We do.

Lastly, I would propose much of what has made it attractive and acceptable to encourage unlimited inquiry for new knowledge—freedom of inquiry in the West—has been that, until relatively recently, really World War II, science has been detached from technology. The scientist could work in his little laboratory with little money and, much like the artist, have comparatively little overall societal

Subcommittee on Science, Research and Technology of the Committee on Science and Technology of the U.S. House of Representatives. Hearings on the science policy implications of the DNA recombinant molecule research issue, May 5, 1977.

Testimony by Freeman J. Dyson,
Institute for Advanced Study, Princeton, New Jersey.

quantitative risk-benefit analysis is useful only in dealing with short-range problems. As an example of a short-range problem, suppose that you have to decide whether to halt a flu-vaccination program this week. Then a risk-benefit analysis makes sense. You can figure roughly how many people are endangered either by being vaccinated or by not being vaccinated, and you can decide on this basis whether to go ahead. As an example of a medium-range problem, suppose that you are choosing whether to build a nuclear or an oil-fueled power-station. Then risk-benefit analysis is less helpful. Nobody can figure reliably the risk that the nuclear station will suffer a core-melt-down or the risk that the oil supply will be embargoed. You can only compare these risks by making a political judgment. When you come to a really long-range problem like the regulation of research with recombinant DNA, then risk-benefit analysis is totally useless. The research is an exploration of the unknown and is likely in the long run to change the course of human history. Any attempt to measure the risks or the benefits analytically is an attempt to predict the history of the next hundred years, including the scientific discoveries that we have not yet made. In plain words, risk-benefit analysis applied to basic scientific research is a delusion. As all of you people in this room should know better than I, government is an art and not a science.

I could end my testimony here. But I do not want to leave you with only a negative message. I believe there is a

toward the security officials. I am arguing that the Atomic Energy Commissioners, by the way they treated Oppenheimer, lost the respect of a great part of the scientific community. I believe further that the lasting alienation that resulted between the Atomic Energy Commission and the scientific community has been a major contributory cause of the difficulties that the nuclear enterprise has encountered in the last decade. So I advise you to watch out when you write the rules governing research with recombinant DNA. Write the rules flexibly and enforce them humanely, so that when some biologist, as brilliant and as arrogant as Oppenheimer, tries to set himself above the rules, he may not be perceived by his colleagues and by the public as a hero.

My second example is taken from a far more remote past. 333 years ago, the poet John Milton wrote a speech with the title "Areopagitica," addressed to the Parliament of England. He was arguing for the liberty of unlicensed printing. I have collected a few passages from his speech which speak to our present concerns. I am suggesting that there is an analogy between the seventeenth-century fear of moral contagion by soul-corrupting books and the twentieth century fear of physical contagion by pathogenic microbes. In both cases, the fear was neither groundless nor unreasonable. In 1644, when Milton was writing, England had just emerged from a long and bloody civil war, and the Thirty Years' War that devastated Germany had still four years to run. These seventeenth century wars were religious wars in which differences of doctrine

before us, even to a profuseness, all desirable things, and gives us minds that can wander beyond all limit and satiety. Why should we then affect a rigor contrary to the manner of God and of nature, by abridging or scanting those means, which books freely permitted are, both to the trial of virtue, and the exercise of truth? It would be better done, to learn that the law must needs be frivolous, which goes to restrain things, uncertainly and yet equally working to good and to evil."

Next I quote a passage about Galileo, since the name of Galileo has been bandied about by both sides in the debate over recombinant DNA. This passage shows that the connection between the silencing of Galileo and the general decline of intellectual life in seventeenth-century Italy was not invented by the molecular biologists of to-day but was also obvious to a contemporary eye-witness.

"And lest some should persuade ye, Lords and Commons, that these arguments of learned men's discouragement at this your order are mere flourishes, and not real, I could recount what I have seen and heard in other countries, where this kind of inquisition tyrannizes; when I have sat among their learned men, for that honor I had, and been counted happy to be born in such a place of philosophic freedom, as they supposed England was, while themselves did nothing but bemoan the servile condition into which learning amongst them was brought; that this was it which had damped the glory of Italian wits; that nothing had been there written now these many years but flattery and fustian.

STATEMENT OF FREEMAN J. DYSON, INSTITUTE FOR ADVANCED STUDY, PRINCETON

Mr. DYSON. Thank you very much.

Let me say, first of all, that I am a complete amateur in recombinant DNA research, also in risk-benefit analysis.

I have been for the last 3 months a member of the Princeton Municipal Biohazards Committee, which is a committee of laymen. We are a committee of 11 of the citizens of Princeton who have been struggling with this issue for the last 3 months. The experience has been extraordinarily heartwarming in many ways. We are not going to be so happy as the committee in Cambridge was, to produce a unanimous report. We have great divergence of views.

You heard one of our members on Tuesday, I believe, Hessy Taft. I don't know whether she talked about our proceedings.

In many ways we have certainly learned a great deal from this experience. And I hope the country as a whole will learn something from this experience, namely, that it is possible for a group of people of widely diverse views to get together and understand each other and respect each other, even when we disagree rather fundamentally.

Let me say in parentheses that nobody who came to talk to us, and we have had witnesses of all kinds, ever claimed unlimited rights of free inquiry. I think not one of the scientists I know claimed such a right. So I think that is a false issue. We all understand that the right to free inquiry is limited.

The question is: How limited. And by what process should it be limited?

I might say also, in response to Don Michael, I think one ought to distinguish very sharply between short-range risk of the experiments now going on, or experiments Princeton University is planning to do, and the long-range risk that will come when we apply the knowledge to the modification of the environment.

I myself feel deeply worried about the long-range consequences of monkeying around with the environment by means of genetic recombination, and even more, of course, monkeying around with human beings. But that seems to me a very separate problem from the risks posed by the experiments now going on. And I wish this distinction would be made more clearly by the people who talk about it.

The statement of Sinsheimer published as an appendix to the volume this committee put out, prepared by the Library of Congress, a short statement called "On Our Own," by Sinsheimer, I thought was the best statement I have yet seen of the risks in this business. Sinsheimer, as you know, is a very cautious individual. But I think he put exactly the right emphasis on the fact risks are very long-range and are something that will be with us from now on more and more as we move toward the direction of the course of evolution. It is not something that comes immediately out of the present experiments.

Let me go to the historical analysis which was the subject of my paper.

I want to say I do not agree with Don Michael that the risks are unprecedented. I don't believe it is the first time that we have come across human activities with irreversible consequences. So I took some examples of questions of rather similar kind that we have had to face

trary, bureaucratic procedure has probably been a great contributory cause for the mistakes later made in the nuclear enterprise.

My second example, which goes back a great deal further, was the regulation of printing of books, which of course again is an irreversible process. I took as my text the remarks John Milton made to the English Parliament in the year 1644. I will not read these to you, because I think they are better read than spoken.

John Milton, the poet, argued very strongly for the free printing of books, in the year 1644. And one has to understand the historical background. This was just a couple of years after England had come through a very bloody civil war, and Germany was still being ravaged by the Thirty Years War, which had been going on then 26 years. So everyone could see very clearly before him what books could do to people.

Mr. THORNTON. Very dangerous now.

Mr. DYSON. These were religious wars in which doctrinal points were killing and mutiliating people on a very large scale. So the Parliament wanted to keep a tight rein on everything that was printed, and they had good reasons for wanting to do that.

Milton argued nevertheless, in spite of these terrible dangers from the printing of books, still one ought to leave it free, and he gave a lot of good reasons. Of course he lost his case, and in fact did not achieve freedom of the printing press in 1644. It took a century or so before that happened.

I think his arguments are very valid. I commend to you his speech at the time. It is rather long and very archaic in its language, but I think it is well worth reading.

The main point I want to leave with you is the first point I quote from Milton, wherein he says: "I deny not but that it is of greatest concernment in the Church and Commonwealth, to have a vigilant eye how books demean themselves as well as men, and thereafter to confine, imprison, and do sharpest justice on them as malfactors. I know they are as lively, and as vigorously productive, as those fabulous dragon's teeth, and being sown up and down, may chance to spring up armed men."

I think that is certainly also true of pathogenic organisms. I think we all agree about that. But the important word in that statement of Milton is the word "thereafter," that books should not be convicted and imprisoned until after they have done some damage. That is essentially what Milton was saying, that what he objected to was the prior censorship, that books would be prohibited even from seeing the light of day.

I think that is essentially the point we have to face in the coming years—whether we are to prohibit experiments before they have that chance of showing they do any harm, or whether we are to just follow the normal rules of legal liability, that if you do something stupid and damage somebody you have to pay for it. And that is a question, of course, to which there is no simple answer. But I think it is the basic problem that this committee and others will have to deal with.

Mr. THORNTON. Thank you very much.

I will at this time declare a short recess.

[Short recess taken.]

Mr. THORNTON. The hearing will come to order.

Mr. THORNTON. We have received testimony that the risk, or the probability at least, of the escape of a micro-organism and its survival in nature—whether or not that micro-organism might be dangerous, is on the order of I believe 10 to the minus 8 which is a very low order of probability.

Now, are we being given a figure that is reliable? Or is someone guessing in giving us that figure? How do we assess that probability figure?

Mr. Dyson, you have your hand up.

Mr. DYSON. We talked about this a lot on our citizens committee. I think we are quite unanimous that such numbers have very little meaning as absolute measurements of risk.

Where they do have meaning is when you make comparisons between different procedures. If you can say you reduce the risk by a factor of 100 by putting on an extra filter, that has some meaning. But attempts to calculate in absolute terms what the probabilities might be, none of us take seriously, for the very reason Don Michael said. We have been through very carefully the history of the accidents that happened in the biology lab in Princeton where these experiments are likely to be done, and we can see what kind of damned fool things go on there, and it has nothing to do with the calculation of probabilities. Someone comes home drunk one night and leaves the door open when it should be locked, which we are all, of course, completely aware of; that kind of thing.

Dr. LOWRANCE. As one who had a tremendous fire that destroyed part of the university laboratory, and who blew out all of the windows on one floor of the building, as one who knews what students can get into, I would say human error is a large part of it.

In this room, in these photographs of the astronauts we have a reminder of the terrible fire that took the lives of several astronauts on the ground. One of the greatest tributes to the space program has been the remarkable safety record of perhaps the most complex engineered systems man has ever put together. Yet even on the ground, not out there on the Moon, but on the ground, the thing blew up like a bomb and took several lives that were highly valuable to society. Those were specific lives. That is a very complicated chain of accident events.

But we have many, many such examples, where the best laid plans went "agley."

Dr. MICHAEL. There is another moral in that example, and that is the enormous and unprecedented effort that went into building fail-safe systems, backups, documentation and documentation on top of it, to avoid accidents. That kind of quality control we've never put into any other social enterprise. And, of course, it took enormous regulation all the way through to accomplish that.

Mr. THORNTON. And enormous redundancies.

And this may also illustrate that it is the unguarded risk, the unguarded contingency, which often occurs. That is not always true. The marvelous ability of the flight that failed to negotiate its way around the Moon and back did point out two things—the redundancies of the system, yet the fragility of the system, at the same time.

Dr. LOWRANCE. I think a point that emerges here is although we cannot make a final balance sheet and say yes, we will do this research,

Mr. THORNTON. Dr. Lowrance—and others—I am going to take your statement about the need for international considerations here and, after disclaiming for you any expression on the part of your employer, the Department of State, do you have any views as to what we should be doing internationally?

Dr. LOWRANCE. Mr. Chairman, several of the Department's executives are looking into the question of international discussion of this issue.

It is a frustrating one, in that discussion is about the only word one can find. We cannot regulate, we have never had a world law that really could regulate actions of citizens of all of the countries uniformly. But I think expansion of the forum of discussion is very, very important. From the very beginning our discussion of the DNA debate, the Asilomar Conference in California had observers from other countries, expanded to include representatives of the Soviet Union.

Mr. DYSON. Not only observers. They participated quite actively.

Dr. LOWRANCE. Right. And this has expanded from the scientific community to the larger community, now obviously to Congress and all the major forums, and you will see much more international discussion.

My feeling is that we not only need rules and regulations but a kind of increased sensitivity. I think, for instance, private research institutions, hospitals, and so on, in our country and others, should be encouraged to examine the issue.

I am glad universities in the last year or so have been induced to examine the problem. The Cambridge debate heated up almost instantaneously—it flashed. It seemed to me that as scientists were trooping in with all sorts of opinions, talking with the council of the city of Cambridge, it would have been appropriate for the mayor to turn to president Bok and say:

Mr. Bok, the question for you is: Can you assure me your entire faculty has examined this issue with sophistication and care and has assured you as president of the university, not a specialist in the issue, but as the head of the institution, that the hazards are under control and that these risks are worth taking?

Of course that happened fairly indirectly, and perhaps even more directly than I am privileged to know. But I think institutional review mechanisms are extremely important at a local level. With all respect to Federal guidelines, but Federal guidelines aside, these are experiments done by graduate students and research assistants, and many full professors who write papers about these things have never themselves done the experiments; and that is the way research goes on in the messy world of the laboratory. So I think institutional review is important.

Mr. THORNTON. Is it reasonable to take some comfort from the observations that the different nations who face this problem of recombinant DNA are closely tracking our own NIH guidelines?

Dr. LOWRANCE. I think that is an accurate perception of what is happening. I am very pleased it has worked that way.

I think it is fair to say there seems to be little overall international disagreement that the issue is important, that there are potential hazards in the research, that there are potential benefits and risks in the research. There is a wide spectrum of opinion. But I think everybody

So as an institutional machine this does work very well, I think. It is close enough to the real problems not to get entangled in legalistic questions, and it is also broad enough to give voice to the people who have real, fundamental objections to what is going on.

In our citizens committee we have proposed that two representatives of the community be added to this university Biohazards Committee, by ordinance, so in the future the broader community will be represented right inside and will get advance information of any experiments that are contemplated, and will have advance information whenever any problems arise.

That seems to us to be a reasonably adequate institutional mechanism for keeping people informed about what is going on.

The other thing I was going to respond to was the international question. We have had, by happy coincidence, a gentleman, Jerome Ravetz, who is a member of the British Genetic Manipulations Advisory Group, actually living in Princeton and talking with us while these discussions have been going on. The Genetic Manipulations Advisory Group is the British response on an institutional level to this problem. It is a very establishment kind of group. It passes judgment on everything that is done in the whole country, and evens everything out very quietly and without any fuss. And of course that answers very well the requirements of the British way of doing things.

Mr. THORNTON. That is the British way of doing things.

Mr. DYSON. He is trying to sell this to us as something appropriate to American conditions. Obviously we feel it is not appropriate to American conditions. In American conditions things have to be much more chaotic. We have to have much more public argument and confrontation. That is the way we feel comfortable.

I think it is important that it is understood that a uniform international regulation of this business will not work. Each country has to choose the institutional machinery with which it feels comfortable. And if there were ever an international set of rules set up it would probably be so inflexible and hard to modify that we would all regret ever having agreed to it.

Mr. THORNTON. I take it you would not advocate such an effort to reach international agreements.

Mr. DYSON. We ought to have very close discussions on the international level so we all know what we are doing. I think it would be a mistake to try to set up international machinery at this point.

Dr. MICHAEL. May I raise one reservation about the present efficacy of institutional review procedures?

I agree we desperately need them, especially in universities. But it has been the experience of some of us who watched this, both at my own university and elsewhere, that there is sometimes enormous pressure on the institution's members to go along with the conventional view of freedom of inquiry and conventional view of "you let me do my research and I will let you do yours."

Any number of people without tenure, younger persons, felt unable to voice their reservations, their data, their critiques. There have been some very courageous ones, too, who have spoken out at personal professional risk particularly in the Cambridge-Boston area. There have also been senior people, who have felt compelled to remain silent because of the kind of dissension they would generate around both the

Dr. MICHAEL. Surely.

Mr. THORNTON. The purpose of a patent is not merely to retard innovation, but also to encourage disclosure and to avoid someone using another route which is available, namely developing a process and keeping it a secret so that no one else has access to it.

Dr. MICHAEL. Again, in this area as with human subjects research, if society, as represented say by Congress, were to decide that this area is sufficiently serious and problematic that we must have disclosure of procedures, it could establish regulations to make this a legal obligation—just as now corporations are required to disclose information about employment and investment, and so forth, which 30 years ago was considered an outrageous intervention in the private practices of the free enterprise process. But in the public interest as it had come to be defined they are legally obligated.

The same thing could hold here. It is a matter of what values are going to operate, what value changes are going to be supported and by whom.

Dr. WILSON. I have been following particularly, of course, the Cambridge question. And, we have a student who particularly, looking a bit from outside, interviewed members of the Cambridge committee. And I think it is worth realizing what that discussion was and what it was not.

Firstly, the program of the university was on a small scale as far as the DNA experiments were concerned, so the degree of containment requested was fairly small and the degree of risk fairly isolated. Even the degree of control that Harvard University had over experiments by its faculty is comparatively small even if they banned them in the laboratory. It was pointed out to me by Professor Meselson that he could do them in his garage in Belmont and no one could stop him. He couldn't do it with NIH funds, but he is not using NIH funds for most of his research.

The other issue involved there was a discussion in the faculty, with a fair amount of dissent; and it was particularly interesting to me to watch the way people who dissented on other questions are in agreement on this and vice-versa. No particular method to stifle discussion, that I could discern, and the people I always thought of as professional dissenters were on the establishment side on this issue, and vice versa. It was quite an interesting mix.

The interesting point was both Harvard and MIT in my view made a major error in this particular matter, and not until sort of a public meeting of the faculty committee, in front of the university, was there any communication with the city of Cambridge. Someone asked the question, "Have you approached the city of Cambridge yet? Are they being brought into it?"

And someone in the audience said "I represent the city of Cambridge and I am here today."

And that was the first representation.

The city of Cambridge was not really discussing DNA research to any real extent. The delays and so on were really a signal to Harvard and MIT that they better bring the city of Cambridge into these issues at an early stage in the future, that Harvard and MIT are not the boss, the mayor of the city of Cambridge is the boss, and although the com-

Dr. MICHAEL. One caveat on that: Increasingly, responsible judgments for tomorrow depend on an estimate of the longer range future. This is the impasse our technology has brought us to. We know we cannot make responsible judgments today without setting them in long-range context, even though we do not know very well what the long-range context is.

It seems to me responsible judgments we make about tomorrow must be done with explicit, overt attention to the alternative futures that were considered in choosing this action rather than that, choosing to go one way rather than another. This is a necessary part of the learning process, the learning society, I spoke of, earlier. Everyone needs to understand the nature of the future context that is to be used as a basis for present action.

As our understanding of the future shifts, it provides input for evaluating the next stage of present action. I don't see how we can evaluate any area of technology if we continue our traditional way of looking into the future a tomorrow at a time. We have to attend to the further future to understand the nature of tomorrow.

Dr. LOWRANCE. If I may comment on it: It seems to me one of the things we are always able to do, that Congress is able to do in this case, for instance, is to decide what we will do first.

I am sure over the next decade we will do many, many experiments. The question is which ones we should do first in order to learn as much as possible about the other experiments we are going to do in 5 years.

I think there is a role for the public, for Congress, for the NIH, in thinking about what kind of experiments we should do first to give us an idea of what territory we face, what business schemes work best as systems, what monetary schemes seem to function more reliably.

A small example is the development of various strange organisms that live only in a strange environment in the laboratory. Properly pampered they can be used in experiments, but if they get out of the laboratory they simply die and do not constitute a hazard.

There is much more to be done, and I think as a start we should not throw up our hands and say we will just have to see how it all goes. Clearly there are some things we can do early on to influence what we do later.

Mr. THORNTON. I think you are saying we should not refuse to explore or move toward the unknown, but that we should do so with great caution.

Dr. LOWRANCE. "Prodding carefully," as you said.

Dr. WILSON. You did not say, but I imagine you implied, the experiments you ought to do first are those that will enable you to estimate better what the risk is, or whether there is a risk at all, and if there is a benefit. In particular, at the moment we have really very little idea whether there is a big risk, a small risk, and whether we can partition the field with some parts having a low risk and some parts having a high risk.

As a layman in this particular field of recombinant DNA research the risks are still very largely unknown, and there are some simple experiments one could do almost at once to identify them. For example, if the mutant objects one might create, spread very rapidly throughout society—almost all we can think of spread rapidly throughout society—

SCIENCE POLICY IMPLICATIONS OF DNA RECOMBINANT MOLECULE RESEARCH

WEDNESDAY, MAY 25, 1977

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:04 a.m., in room 2255, Rayburn House Office Building, Hon. Ray Thornton, chairman, presiding.

Mr. THORNTON. The hearing will come to order. This morning the Subcommittee on Science, Research and Technology continues its series of hearings on the issue of recombinant DNA molecule research. Today we are going to be considering the implications of that research upon our system of laws, the first amendment to the Constitution and other provisions of law which relate to the question of the freedom of scientific inquiry.

We are fortunate in having a very distinguished panel of experts to advise with the committee on this important, complicated and perhaps difficult issue.

Dr. Max Tishler, the 1977 recipient of the gold medal of the American Institute of Chemists, noted in his acceptance speech his distress about what he called new pressures bearing down on research. He is quoted as having said "for the first time in this country, pure research faces the serious possibility of becoming at least in part a hostage of government and a servant of political power." A clear example according to his statement is seen in the controversy over recombinant DNA research. Continuing the quote, "Society no longer accepts one of the basic precepts, on which research is based, namely the pursuit of knowledge is justified wherever it may take us."

Others have voiced similar concerns and variations of opinion and I think a useful analysis can be made which distinguishes or attempts to distinguish the constitutional basis for freedom of expression with the right of Government to regulate action. I think it will be useful for all of us to explore in greater detail the analysis and rationale which does surround this most complicated area.

I am pleased that this group of witnesses can be here this morning. We have been conducting our hearings in a panel format much like a workshop and want to continue that practice. We will begin by welcoming our first witness, Professor Jerome A. Barron, National Law Center, George Washington University.

Mr. Barron, you may proceed.

[Biographical sketch of Jerome A. Barron follows:]

and for scientific research generally. I am not suggesting that the Court has passed on those issues. It has not. But I am suggesting that there is language in the cases the position that Dr. Tishler is representing might take comfort from.

In 1969, the Supreme Court said that the "Constitution protects the right to receive information and ideas." The obscenity cases have some relevant language. But basically, a lot of these things are just quotations out of context. In other words, it does not relate directly to the issue before us.

On the other hand, culling past precedents for relevant remarks is part of the constitutional lawyer's task, and, with that understanding, we can see what the Supreme Court has said on this.

If there is a right to receive, doesn't that necessarily implicate the existence of a right to explore and to investigate? This is less clear. We know that we may watch films in the privacy of our homes free from the censoring hand of the State, although we could not purchase in a store or through the mails those same films.

In the obscenity area, like so many first amendment areas, we find not inflexible dogma, but paradox. The first amendment protects us in the right to use in our homes material we have no right to acquire.

Will similar paradoxes mark the area of first amendment controversy about scientific research? Will the courts say that scientific inquiry is protected as an abstract matter but that local communities also have a right, conflicting though it is, through their zoning powers, to banish particular kinds of scientific research from their borders? Is it possible that a particular line of scientific research is protected and at the same time that the City Council of Cambridge, Mass., may exile it beyond the city limits?

In the DNA controversy, one side asserts that the health of the populace may be immeasurably benefited by DNA research. The other side asserts that the creation of new organisms may menace the continuation of human life in its present form.

When the stakes are presented in such massive and dramatic terms, one most be, I think, more patient with the Cambridge City Council than perhaps many scientists and academics have been.

Last year, the Supreme Court said that it had no doubt that municipalities may control the location of "adult" theaters. The Supreme Court held that a municipality might regulate to keep "adult" theaters out of residential neighborhoods.

Can a community also legislate to restrict the location of laboratories engaging in experiments that will affect the nature and quality of life as well? The State surely has as much reason to be concerned in such circumstances about the location of laboratories as it does about the location of "adult" theaters.

George Wald in his remarks against genetic engineering says that the results of DNA technology will be "essentially new organisms, self-perpetuating and hence permanent. Once created, they cannot be recalled."

If Professor Wald is right—and I do not know—then the first amendment implications of the DNA debate become radically altered. I hope that it is clear, and if it is not, let me stress the point until it is clear: I am not a scientist, much less a biologist, and am not competent to pass on whether George Wald is right or whether his equally dis-

when they are put in the hands of judges are difficult enough when the problems at issues involve delicate matters of social and political analysis and adjustment.

But at least such matters bear some kinship to the legal problems for the resolution of which judges are trained. But in matters involving prophesying the ultimate achievement of DNA recombinant molecule research judges will be found wanting in terms of expertise.

By training the judiciary is particularly unlikely to have the requisite scientific background and knowledge which would make them desirable arbiters of such problems. Similarly, as a group, they are probably too much of an elite to have their ear on the common pulse in terms of providing reliably representative societal reaction to the merits of the controversy.

If a group of non-expert decisionmakers is wanted for deciding the kinds of living organisms which science may permissibly seek, then perhaps in a democratic society the best roll of experts is the voters' roll.

In summary, in matters as specialized, controversial, and important as the DNA recombinant molecule issue, I think a number of basic propositions should be kept in mind:

First, claims of pure scholarship and an unfettered right to communicate have rarely been dealt with by the Supreme Court in absolutist terms. Illustrative is the Court's approach when the Belgian scholar and Marxist Georges Mandel sought entry to the United States, but as a Communist was denied admission. The claims of free inquiry were given serious attention by the Court, but in the end of the traditional leeway accorded to the Federal Government with respect to the admission of aliens prevailed and Mandel was denied admission.

In other words, and I speak now in terms of a student of what the law is rather than what I would have it be, the Court has seldom bowed to the claims that free inquiry prevails before all other values. I am speaking as a reporter on this point.

Many years ago, Justice Frankfurter said that first amendment problems were better dealt with, "by candid and informed weighing of the competing interests * * * than by announcing dogmas too inflexible for the non-Euclidean problems to be solved."

Second, the search for the first amendment resolution to the problem of the permissible societal limits of DNA research will be a futile one if it is thought that the sum of contemporary first amendment case law, doctrine, and principle is clearly for or against uninhibited DNA research.

In matters far less vital to the future of humanity the Supreme Court has recently given tremendous scope to local communities to inhibit the right to communicate. I report that, again, without saying whether it is good or bad.

Third, if first amendment doctrine is in fact used to solve problems of the limits of scientific research, it will, I think, be quickly seen, once tests such as clear and present danger or speech/action are used, that their use will serve only to mask rather than to illuminate what is taking place.

What inevitably will occur in such situations is that the courts will be forced to make a scientific judgment. Is this particular study, this particular laboratory, this particular experiment a hazard to this

Would you like to have the paper which you submitted made a part of the record?

Mr. BARRON. If that is the wish of the chairman and the committee.

Mr. THORNTON. I think it might be appropriate to make your prepared remarks a part of the record. That will be done without objection.

[The document referred to follows:]

THE DNA CONTROVERSY AND THE FIRST AMENDMENT

When an issue of social policy becomes a sufficiently intense matter of controversy, some effort is usually made to identify its constitutional status in hopes that the controversy will therefore somehow be stilled or resolved. But when a matter of novel and difficult social policy must be addressed in constitutional terms, it should be recognized that the battle lines are really not very much altered by the shift from a scientific and/or ethical vocabulary to a legal or constitutional one. So it is with the question of whether the First Amendment protects from governmental regulation the issue of DNA recombinant molecule research.

You quoted Dr. Max Tishler to the effect that society is no longer willing to accept the proposition upon which scientific research is based: "The pursuit of knowledge is justified wherever it may take us."

Whether society has ever been so tolerant is, I think, a matter of some doubt. An issue not quite so large but somewhat related is: has American constitutional law accepted the idea that the pursuit of scientific knowledge is protected wherever that pursuit may lead?

Occasionally, the First Amendment has received a sufficiently broad interpretation from the Supreme Court which might suggest there is blanket protection against governmental restraint for DNA research and for scientific research generally. In 1969, the Supreme Court said that the "Constitution protects the right to receive information and ideas." If there is a right to receive, doesn't that necessarily implicate the existence of a right to explore and to investigate? This is less clear. We know that we may watch films in the privacy of our homes free from the censoring hand of the state, although we could not purchase in a store or through the mails those same films.

In the obscenity area, like so many First Amendment areas, we find not inflexible dogma, but paradox. The First Amendment protects us in the right to use in our homes material we have no right to acquire. Will similar paradoxes mark the area of First Amendment controversy about scientific research? Will the courts say that scientific inquiry is protected as an abstract matter but that local communities also have a right, conflicting though it is, through their zoning powers, to banish particular kinds of scientific research from their borders? Is it possible that a particular line of scientific research is protected and at the same time that the city council of Cambridge, Massachusetts may exile it beyond the city limits?

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words, and I speak now in terms of a student of what the law is rather than what I would have it be, the Court has seldom bowed to the claims that free inquiry prevails before all other values. Many years ago Justice Frankfurter said that First Amendment problems were better dealt with, "by candid and informed weighing of the competing interests * * * than by announcing dogmas too inflexible for the non-Euclidean problems to be solved."

Second, the search for a First Amendment resolution to the problem of the permissible societal limits of DNA research will be a futile one if it is thought that the sum of contemporary First Amendment case law, doctrine, and principle is clearly for or against uninhibited DNA research. In matters far less vital to the future of humanity the Supreme Court has recently given tremendous scope to local communities to inhibit the right to communicate.

Third, if First Amendment doctrine is in fact used to solve problems of the limits of scientific research, it will, I think, be quickly seen, once tests such as clear and present danger or speech/action are used, that their use will serve only to mask rather than to illuminate what is taking place. What inevitably will occur in such situations is that the courts will be forced to make a scientific judgment. Is this particular study, this particular laboratory, this particular experiment a hazard to this particular community? A pragmatic inquiry will be the real touchstone of decision in such cases, and I do not think it can be otherwise.

Fourth, if traditional First Amendment tests are going to be used to resolve the question of the continuation of DNA research, I think it is better to use as clear a balancing test as possible. The identification of the issues involved is much more likely to become visible if we do not pretend that the symbolic force of the First Amendment is very heavily with one side and against another. This is not a contest between Galileo and the Know-nothings. It is a problem of how many people in society should share in decisions which might reshape the nature of life. If the problem is presented in that fashion, then I think it is revealed in its true First Amendment significance. If the First Amendment exists to maximize participation by all the citizenry in all the decisions which affect their future, then we should be wary of arguments which in the name of free inquiry are likely to move society and life itself in a particular direction beyond effective recall by any popular referendum.

In short, legislators are wise to be concerned that too much easy and ill considered legislation may result in crippling research that might provide dramatic advances in the cure and treatment of disease. One does not err in giving the claims of free inquiry enormous scope. But a claim of free inquiry by science should not be used as an obstacle to shield from oversight and participation by the electorate at large ultimate decisions which go to matters of such grandeur as the revision and creation of life. Such matters should not be reserved solely for decision by scientists. To describe these issues in First Amendment terms, it must be understood, does not in itself make a case for exclusively reserving them for scientific decision making. There is, in my opinion, no basis in First Amendment case law for such a conclusion. Similarly, approaching the DNA controversy in terms of the First Amendment should not be interpreted as reserving ultimate decisions as to the future of such research for the judiciary. In my view, the primary judgment in setting parameters for such experimentation should be at least at the outset a matter of legislative judgment. If thereafter either science or a section of the citizenry feels that the exercise of the legislative judgment has done violence to some fundamental human right, whether that right involves the freedom of the intellect or the security of the person, the courts are then appropriate parties to resolve the conflict. But they are appropriate bodies to resolve this conflict only if we realize that in this area judges, like the rest of us, will write on a fairly clean slate. In sum, with respect to the DNA controversy, the First Amendment has no favorites. There is as much case law to support the proponents of the research as there is to support those who would regulate it.

We would like to move forward fairly quickly to hear from each of the other panelists. However if there are any clarifying questions that need to be asked, we will have them now.

Mr. HOLLENBECK. No questions at this time.

Mr. THORNTON. I would like to recognize Mr. Berns. We are pleased to have you attending our subcommittee hearings this morning. Pro-

10. "Replies to Schaar and Wolin: III", The American Political Science Review, Vol. 57 (March 1963), pp. 155–156.
11. "Reform of the American Party System", in Robert A. Goldwin (ed.), Political Parties, U.S.A. (Chicago: Rand McNally and Co., 1964).
12. "Racial Discrimination and the Limits of Judicial Remedy", in Robert A. Goldwin (ed.), 100 Years of Emancipation (Chicago: Rand McNally and Co., 1964).
13. "The Constitution and the Migration of Slaves", Yale Law Journal, Vol. 78 (December 1968), pp. 198–228.
14. "Freedom of the Press and the Alien and Sedition Laws: A Reappraisal", in Philip B. Kurland (ed.), The Supreme Court Review, 1970, pp. 109–159.
15. "The New Left and Liberal Democracy", in Robert A. Goldwin (ed.), How Democratic is America? (Chicago: Rand McNally and Co., 1971).
16. "Beyond the (Garbage) Pale, or Democracy, Censorship and the Arts", in Hary Clor (ed.), Censorship and Freedom of Expression (Chicago: Rand McNally, 1971).
17. "Pornography vs. Democracy—A Case for Censorship", The Public Interest No. 22, (Winter 1971), pp. 3–24. (Reprint of item above).
18. "Oliver Wendell Holmes, Jr.", in Frisch and Stevens (eds.), American Political Thought (Scribners, 1971).
19. "Free Speech and Free Government", in The Political Science Reviewer, Vol. II (Fall 1972), pp. 217–241.
20. "The Constitution and a Responsible Press", in Harry M. Clor (ed.), The Mass Media and Modern Democracy (Rand McNally, 1971), pp. 113–135.
21. "Justified Anger, Just Retribution", IMPRIMUS (1974).
22. Religion and the Founding Principle", in Robert Horowitz (ed.), The Moral Foundation of the American Regime (The Univ. of Virginia Press, 1977).

C. Book reviews

I have published book reviews in the following journals: The Journal of Politics, The Western Political Quarterly, The Louisiana Law Review, The Tulane Law Review, The Yale Review, The Virginia Law Review, The Midwest Journal of Political Science, The American Political Science Review, The Columbia Law Review, Yale Law Journal, Cornell Law Quarterly, Virginia Quarterly Review, Stanford Law Review, Georgetown Law Journal, and "The Intercollegiate Review.

D. Journalism

"The Essential Soul of Daniel Berrigan", National Review, Nov. 9, 1973; "Thinking About the City", Commentary, October 1973; "The Importance of Being Amish", Harper's, March 1973; and "The Press: Absurdity at the New York Times", Harper's May, 1973.

Work in progress: A book, Crime and Capital Punishment, to be ready for publication, Fall, 1977.

Graduate students (University of Toronto): Paul Norton, "The Radical Critique in American Political Science", principal supervisor. Thesis accepted, 1976, Ph. D. granted, 1977, and Frederick Morton, 'Equal Protection and the Problem of Gender", principal supervisor. Work in progress, spring, 1977.

Service on committees, etc.: Council, School of Graduate Studies, and Executive Committee, Div. II School of Graduate Studies.

Miscellaneous: I have delivered papers at a number of learned society meetings, and have served as program coordinator of the panels on constitutional law, American Political Science Association, 1977.

STATEMENT OF WALTER F. BERNS, DEPARTMENT OF POLITICAL SCIENCE, UNIVERSITY OF TORONTO, CANADA

Mr. BERNS. I knew little about this at the outset when Mr. McCullough called me. I picked up my daughter's biology textbook to see what DNA recombinant molecule research was. I am, as you say, a political scientist. I have had an interest in constitutional law and within the field of constitutional law, a particular interest in the law of the first amendment. I presume I was invited to testify because the question arises as to whether DNA recombinant molecule research is a

protection, religious speech or opinion was to enjoy the most absolute freedom.

But even here there were limits, according to Jefferson. When religious opinion breaks out into overt acts (this is from the "Notes on the State of Virginia") for example, when the opinion that a wife must immolate herself on the husband's funeral pyre leads to her doing so, then the law might properly intervene, without violating the principle of freedom of religion.

There is a recognition that speech has consequences and the law is entitled to weigh those consequences, determining whether they are good or bad, whether they are in the public interest or contrary to it.

For example, the first amendment permits both Congress and the States to decide whether pornographic speech has deleterious consequences. I think the same principle applies as well to scientific speech.

What I am saying here is that nothing in the first amendment, as I read it, forbids Congress to address this question of scientific research from the point of view of what is good for the United States rather than from the point of view of constitutional rights. I can illustrate the occasional inappropriateness of viewing certain questions as one of constitutional right by reminding the committee of what the Supreme Court has done with the abortion question.

Once it was decided in 1973 that a woman had an absolute constitutional right up until the seventh month of her pregnancy to an abortion, it followed automatically that whatever right the father may have is subordinated and must be understood to be subordinate to the mother's. Hence when there is a conflict of these, the father's right must give way to the mother's.

This was so decided by the Supreme Court last year in *Danforth* v. *Planned Parenthood of Central Missouri* (96 S. Ct. 2831), where the Missouri law requiring a father's written consent to an abortion was held to be unconstitutional.

What is omitted in this formulation of the question—father's right, mother's right—is I think the family. Where is the family in this formulation? There is the question as to whether the family does not have some role in constitutional democracy in the United States. I shall have a few words to say about that in a moment. I merely want to make the point that not all questions are comprehended within the context of constitutional rights.

I am arguing that what may be true of the abortion question may also be true with respect to scientific research.

It seems to me that something of importance might be left out if we begin with the assumption that there is an equivalent right to engage in scientific research. We want fairly to raise and consider the questions involved and these are: What are the hazards involved and what are the benefits promised?

We want to be able to consider these questions unhampered by severe restrictions arising from constitutional provisions. My opinion is that the hazards are sufficiently grave so as to place on the scientists the burden of persuading us that the benefits are likely to outweigh the hazards.

The benefits promised are essentially an improvement on our present condition. I wonder what is so unsatisfactory about our present condition to justify the risks involved in attempting to improve it.

Mr. BERNS. What concerns me is that science may be crossing a barrier that is better not crossed. Science has transformed the world outside man and is now moving into an area where it may transform man himself. The natural world, what we see around us, can be said to be composed of three sorts of things. Things made by God, things made by man, artifacts, and man himself. Man is made by God but he is himself a maker. Now if we clone human beings, we in a sense make man. As Leon Kass asks, "Is there possibly some wisdom in that mystery of nature which joins the accomplishment of sex, the communication of love and the desire for children in the very activity by which we continue the chain of human existence?"

Making babies without sex surely threatens the family and the family is the one institution that causes us to care about our country. It gives us a sense of continuity with the past and a sense of commitment to the future. I must say that as the father of three children, I in a sense have given hostages to fortune. If I did not have those children, I could view the future with a great deal more insouciance than I do. It is precisely because I have children that I have left those hostages, that I am a member of a family, that I am concerned specifically about the welfare of the United States of America.

In other words, I am making the point here without further elaboration that there is a connection between the family, which is under attack from all sorts of forces, a connection between the structure of the family and the well working of the United States.

That family is also being threatened, I think, by certain kinds of scientific research.

Finally, the issues are such that Congress should devise some constitutional procedure for encouraging intelligent and relevant speech about scientific research. We can no longer assume that this research will be to our benefit. The issue is not simply one of public health and arises not merely out of DNA recombinant molecule research.

I am ending here by saying that the committee should devise some institutional procedure for encouraging intelligent and relevant speech about scientific research. I am not persuaded that we now have such an institution, and I am not sure what form it should take—whether it should be patterned on the adversary system of the courts or the investigative system of a Congressional Committee—probably the former. But what I think the committee should do—and I can only promise I will give it thought myself—is to come up with some structure in which it is possible to raise questions that I think have not been sufficiently raised yet because so far as I can see from the Report, the question has been raised in the area primarily of public health. I don't minimize that but there are issues other than public health issues involved in scientific research. Thank you very much.

Mr. THORNTON. Thank you very much, Dr. Berns. I appreciate that testimony. Unless there are clarifying questions, we will proceed to hear from Mr. Emerson, the linus professor of Law Emeritus at Yale Law School.

Your prepared testimony will be made a part of the record of these proceedings without objection. I would like to ask you now to go forward with your presentation.

Mr. EMERSON. Thank you very much, Mr. Chairman.

[Biographical sketch & prepared statement of Mr. Emerson follows:]

TESTIMONY OF THOMAS I. EMERSON, LINES PROFESSOR OF LAW EMERITUS, YALE LAW SCHOOL
BEFORE THE HOUSE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY, MAY 25, 1977

The constitutional problems involved in governmental regulation of scientific research have never been directly addressed by the Supreme Court. Although numerous laws and regulations affect various aspects of such research, the far-reaching issues that are raised by current proposals for controlling the use of recombinant DNA technology present novel constitutional questions. My ideas on the subject are wholly tentative, and I reserve the right to change my mind. Moreover, my conclusions can be set forth here only in the briefest manner.

The primary constitutional provision applicable is, of course, the First Amendment. That fundamental guarantee has the broadest reach and imposes the strictest limits on the kind of governmental action we are considering here. Other consitutional requirements -- including due process, equal protection, and perhaps the right of privacy — may also be involved. In general, however, these provisions of the Constitution perform a supplemental function here. They have an impact only where the First Amendment cannot be invoked. Hence they are largely limited in scope to the detailed issues that will arise after the basic framework of control has been shaped by the demands of the First Amendment. My discussion in this initial presentation, therefore, will deal exclusively with First Amendment issues.

I will also consider the questions in terms of control over recombinant DNA research.

The Supreme Court has consistently applied the First Amendment in accordance with this original intention. Over 50 years ago, before the First Amendment had been made applicable to the States, the Court held unconstitutional a State statute that made it a crime to teach languages other than English in the public grammar schools, condemning such restrictions upon the freedom of teachers to teach and of students to learn as a violation of due process.[2] Subsequently the Court made clear that the First Amendment embodied the basic principles of academic freedom. In Sweezy v. New Hampshire, reversing a contempt citation for refusing to answer questions before a legislative investigating committee concerning the contents of a university lecture, Chief Justice Warren declared:

> "The essentiality of freedom in the community of American universities is almost self-evident. No one should underestimate the vital role in a democracy that is played by those who guide and train our youth. To impose any strait jacket upon the intellectual leaders in our colleges and universities would imperil the future of our Nation."[3]

This theme has been sounded again and again by the Supreme Court. Thus in Keyishian v. Board of Regents the Court, striking down a State loyalty program for teachers, stated;

> "Our Nation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment, which does not tolerate laws that cast a pall of orthodoxy over the classroom."[4]

And in Epperson v. Arkansas, where the Court invalidated a statute that prohibited teaching of the theory of evolution in the public schools,

2. Meyer v. Nebraska, 262 U.S. 390 (1923). See also Pierce v. Society of Sisters, 268 U.S. 510 (1925).
3. 354 U.S. 234, 250 (1957).
4. 385 U.S. 589, 603 (1967).

involves the search for truth in its primal form. The fact that the researcher works physically with complicated equipment does not deprive the conduct of its character as expression. In similar fashion a telescope is used to study the stars, an accelerator to study nuclear particles, a public address system to carry on a public meeting, and a xerox machine to make copies for distribution.

The more difficult question is the classification of experimentation. Experimentation is a vital feature in the development of new information, ideas, and theories. This is particularly so in the physical sciences. One must conclude that it is often an integral part of scientific research, that is, a part of the system of freedom of expression. Analogous conduct is the marching in a demonstration, the publication of a newspaper, and the organization of a political party. Although all such conduct involves more than sheer thinking or verbalization, nevertheless it is an essential feature of a system of free expression.

On the other hand, at some point experimentation clearly moves into the realm of action. Just as a political assassination has an element of expression but is basically action, so an experiment to test a theory of nuclear energy which might blow up a city, or contaminate the atmosphere of the whole world, is also predominantly action. The line has to be drawn on the basis of all the facts in a particular case and in light of the proper function of a system of freedom of expression in a democratic society.

On the basis of present information available to me it is difficult to state more specifically what forms of experimentation should be classified as expression, and what as action. It does seem clear,

government had a right to prevent. For several reasons, however, the clear and present danger test does not seem to me acceptable. In the first place the Supreme Court has rarely employed the clear and present danger test in recent decades, and may be said to have abandoned it.[6] Secondly, as applied to the problems before us, the clear and present danger test would amount to little more than a general balancing of interests test. And, if balancing is to be employed, a more carefully structured balancing test, which will be discussed shortly, is available.

A second possible doctrine is the simple balancing of interests test. Under this doctrine the individual and social advantages of engaging in the DNA research contemplated would be weighed against disadvantages. The Supreme Court has applied such a balancing test in the past, and still continues to do so.[7] Nevertheless, as just observed, more sophisticated balancing tests have now come into use and would seem to be vastly preferable.

The orthodox doctrine most acceptable, and the one I believe the Supreme Court would adopt, is a structured balancing test. According to this test, when fundamental First Amendment rights are involved, governmental regulation is valid only when the government sustains the burden of proving (1) that there are "compelling reasons" for the regulation, and (2) that the objective cannot be achieved by "less drastic means", that is, by more narrowly drawn regulations less

6. See Brandenburg v. Ohio, 395 U.S. 444 (1969). But cf. Nebraska Press Association v. Stuart, 427 U.S. 539 (1976).
7. See, e.g. Bigelow v. Virginia, 421 U.S. 809 (1975); Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

to the health or safety of the community would be constitutionally subject to regulation.

In between lies a broad area which would be dependent upon the facts demonstrated in the particular case. Thus the degree of risk that would be needed to justify governmental regulations could only be determined in the light of concrete information. And presumably the more serious the risk the less degree of certainty that would be demanded. I do not have sufficient information in my possession to move beyond this degree of generalization.

The second portion of the structured balancing test requires that the government regulation imposed be the narrowest necessary to achieve the objective. This seems to me to involve two kinds of limitations on governmental action. One is that the governmental restrictions be kept to a bare minimum. This would require, for example, that where possible the control be temporary rather than permanent; that where possible it be regulatory rather than prohibitory; that it involve the least onerous burden; that licensing or other forms of prior restraint be utilized only as the last resort; and so on.

The other requirement of the least drastic means test, in my opinion, is that the controls be imposed only from one source, which must be the Federal government. The advantages of decentralization in many situations are obvious. But where delicate issues of academic freedom are involved, as in the DNA research controversy, the fewer sources of governmental restriction the better. I think there is little doubt that a failure

V.

In conclusion, one can say that a democratic society is not incapacitated by the Constitution from protecting its vital interests so far as the development of scientific research is concerned. As a matter of fact, though the Supreme Court has not yet been directly involved, various forms of control are assumed or accepted as wholly legitimate by our society. No one would question that Nazi-type experiments upon human beings, no matter what their scientific value, are legally beyond the pale. The Atomic Energy Act regulates in closest detail the posession and use of certain substances, for scientific and other purposes, where unregulated activity might lead to public danger. Various drugs and other materials, useful in scientific research, are likewise controlled. Any actual physical dangers inherent in DNA research can be forestalled on the same basis.

Yet in doing this it is imperative that our long tradition of freedom of research and freedom of inquiry be preserved. For this purpose the First Amendment stands as a bulwark against small encroachment or massive attack. Regardless of what theory of the First Amendment is employed, the concrete results seem to be strikingly similar. The right to pursue knowledge and to expound ideas remains free. The right to engage in experimentation that phsycially imperils the health or safety of the community may be restrained. The difficult problem will be to maintain an appropriate balance between the two principles.

This would mean in essence that the theoretical development of DNA research and the discussion of those ideas, contrary to Professor Berns, could not be prohibited. I think it would be shocking so say that a legislative effort should be made to prevent further concern with these matters.

Dr. Berns objects to man transforming himself but the whole basis of civilization has been the transformation of man. It would seem to me that it would be totally contrary to the intention of the framers of the Constitution and to our future as a democratic society to attempt to impose restrictions on thinking and talking and theoretical development of those ideas.

Now I agree that the Supreme Court has not adopted my theory of full protection and let me therefore discuss briefly the issues in terms of more orthodox Supreme Court theories.

Of course under any theory one has to determine whether or not the conduct involved is covered by the first amendment at all. So to some extent the Supreme Court orthodox theories all involve an initial determination as to whether or not the activity that is under consideration is speech or expression, or whatever you want to call it, so that it is protected to some degree by the first amendment.

The difference is that, whereas my theory and the one adopted by Justices Black and Douglas would require at the outset a rather careful definition of what is expression and then give full protection to expression, the orthodox Supreme Court theories are much less concerned with a careful definition of what is expression. They are willing to say that almost anything which has an expressive element is entitled to some protection under the first amendment. Then they use other doctrines as the key doctrines to determine what the extent of that protection will be. So that I do not think there would be any doubt that the Supreme Court would bring within the framework of first admendment consideration all forms of experimentation for scientific research.

Beyond that point, then, orthodox theories look to various doctrines. In my paper, I analyze very briefly the clear and present danger doctrine and the ordinary balancing test, and I indicate reasons why I think those are unacceptable.

The doctrine which I think should be applied, and which I think the Supreme Court would apply on the basis of its decision concerning the Presidential Campaign Fund Act, is what I call a structured balancing test. This is composed of two elements. I should add that the burden of proof is on the Government when it initiates regulations that impinge on first amendment rights.

There are two elements: Compelling reasons and less drastic means. First, the burden of proof is on the government to show compelling reasons for its regulation. Second, it must use the least drastic means that can possibly be employed in order to attain the objective.

If we apply that test to this situation it seems to me that although Professor Berns may individually feel that there are compelling reasons for not continuing further into the theoretical aspects of recombinant DNA research, nevertheless constitutionally it is quite clear that such reasons are not compelling. The whole basis of the first amendment, as I attempted to explain before, indicates that a reluct-

with respect to procedural due process and first amendment due process and other methods of procedure and so forth. I think these checks are indispensable and therefore any system of regulation would have to include a rapid and effective system of judicial review.

I would think also that procedurally it woud be necessary to set up machinery—here I agree with Professor Berns that we have not really thought about how this should be done—machinery for the decision-making process that is nonpartisan so far as possible and more specifically perhaps that is sensitive to the first amendment issues. That also would be a part of first amendment due process.

Mr. THORNTON. When you use the word "nonpartisan," you mean "not politicized"?

Mr. EMERSON. Yes; and avoid the partisan political implications and as far as possible the excessive emotional concerns that can be aroused with respect to it. I don't mean purely expertise. I think that has to be a part of it. But some way to isolate the problem from the type of emotional and irrational opposition that sometimes develops should be devised.

I realize that is not exactly in line with pure democratic principles, but after all, the theory of the first amendment is that the minority has the right to speak. There is no particular point of extending protection to the right of the majority to speak. They always can speak. To carry out that particular aspect of the first amendment, I think, requires some sort of institution that is sensitive to what the problems are.

What I would say therefore is that under the first amendment, under either theory, the basic research, the basic exploration of ideas, and so on is subject to absolute protection under the first amendment. Experimentation is subject to similar protection within limits. But there are areas where experimentation is subject to restriction. And the place at which I draw that line, at least for the time being, is where experimentation involves a substantial physical danger to the health and safety of the community.

I think that the regulations can be worked out giving effect to those basic ideas and I think the impact of the first amendment on that process should be a very strong one.

Thank you.

Mr. THORNTON. Thank you very much, Mr. Emerson. I would like to ask at this point, immediately following your presentation and the thorough paper which you have presented, whether the language of *United States* against *O'Brien*, the 1968 case before the Supreme Court, which stated "a Government regulation is sufficiently justified if it is within the constitutional power of government, if it is further an important or substantial governmental interest, if the governmental interest is unrelated to the suppression of free expression, and if the incidental restriction on alleged first amendment freedom is no greater than is essential to the furtherance of that governmental interest"—could be considered applicable in support of the analysis you have given that requires whatever objective is to be achieved must be achieved by the least drastic means, measured somewhat along the lines you have suggested?

Mr. EMERSON. I think the *O'Brien* case is a disaster.

Mr. THORNTON. I know Mr. Douglas dissented from that case and you have quoted with approval his language.

ters which stems from my participation as one of the four nonscientists invited to participate in the Asilomor conference, my work as a consultant to Dr. Fredickson, the Director of NIH with respect to this problem and only parenthetically to my role as a teacher of constitutional law.

I think the first thing that is worth noting is that this entire problem of First Amendment protection of recombinant DNA research has arisen almost exclusively within the scientific community itself.

To the best of my knowledge, we are talking about this issue because some scientists who are not constitutional scholars have injected this issue into the arena of the discussion. Because it has arisen that way and not within the area of traditional constitutional scholarship, the issues are rather fuzzy. No distinction has been drawn between scientific inquiry or scientific research per se and scientific experiments and technological applications that are important to developing scientific knowledge but which impinge upon the health and safety of the public and environmental safety.

Second, there has been a great deal of fuzziness on the question whether or not we are talking about the right of the individual scientist to do the kind of research he wants to do or whether we are talking about a constitutional right of individual scientists to feed at the public trough.

Putting that another way, whether somehow a constitutional right to freedom of scientific inquiry means that the Government has a constitutional duty to fund scientific research.

Indeed, there are some scientists who have seriously made that argument. Third, a fundamental fuzziness concerns the question assuming that some regulation is required—and I think almost all of the practitioners of recombinant DNA molecule research and technology would say that some regulation is required—should it be self-regulation such as the biomedical community has long been accustomed to and entrusted with, or should it be regulation by Government?

Fourth, there is the problem of where the burden of proof lies, assuming it is correct as professor Emerson said that there must be some compelling reason for that regulation that restricts research or experimentation. Who makes the decision whether there are compelling reasons?

Is the decision to be made by the scientific community or by the legislature? The scientists would argue obviously to protect their own preserve that the decision should be made by the scientific decision or at least that the legislature should do what the scientific community tells them to do.

In any event the most remarkable part of this entire matter is that the issue of the first amendment has been raised at all in connection with recombinant DNA molecules. Surely the scientists know as well as we do that there are countless precedents for restrictions on research.

Professor Emerson pointed out that the Atomic Energy statutes restrict scientific research with respect to nuclear materials. There are restrictions on research into new drugs. Already there are restrictions on human experimentation. There are restrictions on vivisection in connection with scientific research.

There are zoning restrictions. To the best of my knowledge, no one has ever argued seriously that any of these restrictions implicate first

research that is most clearly benign and to discourage that research that appears to be the least benign.

I don't think there are any constitutional problems of any kind that is—that are involved in that proposition. Nor do I think that so long as there is a real rational basis for any concern that experiments in recombinant DNA molecules may be hazardous to the health and safety of the public or to the environment that Congress and the city of Cambridge, Mass. have the full constitutional power to regulate, restrict or prohibit those activities from occurring.

Thank you.

[The document referred to follows:]

Two and a half years ago a group of scientists called upon their colleagues throughout the world to establish a moratorium on certain kinds of experiments involving recombination of DNA molecules. This moratorium, apparently universally accepted, the subsequent NIH guidelines imposing positive restrictions on such experiements, and prohibitions suggested or adopted by various state and local governments, have all stimulated discussion as to whether such restraints in some way violate what has been characterized as "the right to scientific inquiry." More specifically, it has been suggested that scientists have a right to pursue knowledge and this right is of the same dignity as freedom of speech and of the press guaranteed in the Constitution of the United States.

It is not surprising, therefore, that upon establishment of the AAAS Committee on Scientific Freedom and Responsibility, that committee would turn its attention in part to the question whether there are in our American system of government and law any boundaries to scientific freedom and, if so, where these boundaries are to be found. Specifically, a Subcommittee on the Boundaries of Scientific Freedom, of which I am Chairman, has been created to look into this matter.

It is impossible in the 20 minutes allotted to me to give you a complete exposition of the boundaries of freedom of speech as enunciated in Supreme Court decisions. Suffice it to say, some kinds of speech enjoy the protection of the First Amendment; other kinds of speech do not. Even where speech does enjoy such protection, the degree of protection is variable. A distinction of crucial significance is that between speech and action. Speech emanating from the vocal chords is generally fully protected, but amplified speech is not; one is constitutionally protected in cursing the flag or a draft card, but he is not protected when he rips or tears it; one is protected by the First Amendment when he engages in vigorous debate with a foe, but not when he uses language (fighting words) calculated to provoke a violent response; one may discuss aircraft hijacking in his own home or office, but not when he is sitting in a commercial aircraft.

Such precedents are helpful in drawing the constitutional boundaries of scientific freedom. Surely a scientist has the freedom to think, to do calculations, to write, to speak, and to publish. When, however, the scientist leaves the area of such

Again, the freedom of speech analogy is instructive. When we are operating in the realm of pure constitutionally protected speech -- or abstract or theoretical scientific research -- a proponent of restrictions must carry a heavy burden of proof. There must be a compelling governmental interest in the restriction (e.g., a clear and present danger to be protected against), and the restriction itself must be designed to intrude to the minimum extent possible on the constitutionally protected right. As, however, we move down the scale towards action and experimentation, the burden shifts dramatically, and no more than a rational basis will be required to sustain the constitutionality of the restriction. For example, obscenity is not protected by the First Amendment. Therefore, it is not necessary for government to show a clear and present danger before it acts to restrict obscene speech. Obscenity may be prohibited without any showing that obscenity is harmful; indeed, it is not even necessary to show that the government actually thinks that obscenity is harmful; it is enough that government <u>may have believed</u> obscenity was harmful. This attitude reflects the currently prevailing judicial attitude that, at least where no constitutional limitation on government power is operative, the courts will

major expansion of human technology has been suppressed for political reasons." In the same vein, some scientists seem to believe that it is immoral or wrong if the government is really motivated by a fear that resulting scientific knowledge will be misused. Personally, I do not understand why if it is legitimate for government to fund research because it hopes for constructive knowledge it is illegitimate for government not to fund research because of concern that the resulting knowledge will be destructive. Indeed, as I have argued elsewhere, it is probably not realistically possible for our democratic society to impose timely and effective regulation over abuse of knowledge resulting from government-sponsored research and development.*

When government, for whatever reason, chooses not to fund a particular kind of scientific research, it is not interfering with scientific freedom. Scientists remain perfectly free to do this research if they can find the money elsewhere. On the other hand, a direct prohibition or restriction on scientific research may indeed represent an infringement of scientific freedom.

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* See, for example, my paper "Law and Genetic Control: Public Policy Questions" in Volume 265, Annals of the New York Academy of Sciences, Ethical and Scientific Issues Posed by Human Uses of Molecular Genetics, pp. 170-175 (1976).

It is not clear to me why, in the face of such precedents, the scientific community has become so edgy about scientific freedom in recent months. In any event, the Subcommittee on the Boundaries of Scientific Freedom, which I chair, hopes to examine precedents such as those I have just enumerated in which significant restrictions on scientific research have been adopted, some with the apparent acquiescence, at least, of the scientific community. We hope it will be possible through examination of these cases to acquire a better understanding of the decision-making and negotiation process through which such restrictions have been adopted.

When I began this talk, I made it clear that I would be discussing the boundaries of scientific freedom as a matter of constitutional law and not as a matter of public policy. It is important to distinguish clearly between these two concepts. For example, I personally would argue in favor of the constitutionality of the Cambridge prohibitions against recombinant DNA molecule experiments, but I would also argue against such prohibitions on policy grounds. In recent years, we have become excessively accustomed to looking to the courts to protect what we perceive to be our rights, and we have lost sight of the fact that the first, and in many cases the only, line of defense of these rights is

Mr. THORNTON. Thank you very much, Professor Green, I think it might be a bit difficult to pull together a synthesis from the presentations this morning. However, there probably are some areas in which agreement may be expressed and some areas where we may want to focus more sharply upon the divergent views in order that we may have them clearly reflected in the record.

In that regard, Mr. Hollenbeck has had to leave for another appointment and has asked for permission to submit questions in writing. I would hope that members of the panel would agree to respond to such additional questions in writing as may be submitted by members of the committee or by staff.

Is that agreeable?

Mr. BARRON. Yes.

Mr. GREEN. Yes.

Mr. EMERSON. Yes.

Mr. BERNS. Yes.

Mr. THORNTON. Picking up at the conclusion of Professor Berns' testimony, I don't think there is likely to be any appreciable constitutional or legal support for an idea that the scientific community has a right to unrestricted governmental funding or any kind of governmental funding for research activities.

And further, I doubt that there is a constitutional protection, if you want to call it that, against the Government imposing such regulations or rules for gaining this research money which is coming from the public treasury as it may wish to impose, assuming that those regulations are not themselves in violation of some other constitutional right. Is there disagreement?

Mr. EMERSON. I don't think it is 100 percent. I would agree generally that there is no obligation to fund money. However, there is a basic constitutional doctrine that has existed for a long time, the doctrine of unconstitutional conditions.

If the Government does fund the money, then there are certain limitations as to the conditions it can attach to the funding of that money. For instance, this very question is now before the Supreme Court in the abortion cases which involve the issue of whether or not welfare funds can be forbidden in the use of abortions unless they are therapeutic abortions.

There is no obligation on the part of the Government to provide welfare funds but if they do provide them, can they provide them on the condition that the constitutional right to abortion will not be funded?

When you get into the area of freedom of inquiry and freedom of expression, it becomes very, very complicated and usually the issue would not arise. But it might be that if funds are made available generally for scientific purposes but they were denied for some particular reason which violated the first amendment freedom of inquiry, it might be that that might be unconstitutional. I agree it would be a very narrow area.

Mr. THORNTON. I tried to hedge my question to indicate that if the conditions were unconstitutional, that there might be a problem. I appreciate that decision. Are there other comments?

of courts here. I meant to suggest that as an initial matter it should be bad, undesirable, if we went away from this problem to take a view such as has been suggested that there can be no regulation here at all.

This is not to suggest that there should be regulation, or that it should be extensive, that one should not have that great respect for less drastic means and less onerous alternatives that Professor Emerson is talking about. But it does mean that you ought to first make the resolution of the issues involved a matter of legislative judgment.

I would not like these issues to come to the court at first blush. When I was making a statement about institutional competence and the lack of scientific expertise of judges, all I mean to say is that as an original proposition, I would rather it filtered through the legislative proposition first and then went to the courts.

Mr. THORNTON. I appreciate the confidence that that implies for the legislative process.

Mr. BARRON. Let me complete the circle here. That was not the intention of those remarks. What I mean was I feel that in this issue, maybe what is separating Professor Emerson and myself, is the extent to which the first amendment theory is an egalitarian theory. If you are interested in participation in issues as vital as these, it is best they go to the legislature.

Mr. BERNS. I would like to support that statement because in a way it says the same thing that I said inadequately in my prepared statement. I doubt very much whether the issues as I see them can be properly presented to a court even with the practice of class action suits or amicus briefs and so forth.

I am not persuaded that this way is a proper way. I would much rather see a legislative record before the issue is presented in the form of litigation.

Mr. YEAGER. Could I ask a question for clarification?

My recollection is that the court traditionally did not concern itself with a lot of things in the past until some people came along with certain expertise and introduced it. As I recall, Brandeis often brought economics and labor relations into his rationale. Mr. Warren introduced a concept of accepting psychological opinion as part of a decision and so forth.

Up to that time, such considerations had not been used, as I understand it, in most of the Supreme Court decisions. They had not undertaken to utilize basic data in economics or psychology or whatever until they were faced with a problem that seemed to require it.

Is this different? How do you differentiate now that we are talking about science, or at least hard science as against the soft sciences?

Mr. BARRON. One difference or one thing to think about is in the first Brandeis type briefs, there you had economic data being used to justify legislation that was already in existence. This was to support legislation. The original Brandeis brief——

Mr. YEAGER. Was this Federal or State?

Mr. BARRON. Well, most of it was State. In other words you had the legislative judgment made first there which is I think congenial to what I was talking about.

Mr. BERNS. I would like to add something, Mr. Yeager. When counsel first presented what came to be known as the Brandeis brief, then

Mr. THORNTON. On that point we have agreement on that between three of the panelists. Dr. Berns, you addressed the question whether there should be Federal preemption?

Mr. BERNS. I have not but I would certainly agree. Congress has the constitutional authority to do so in my opinion.

Mr. THORNTON. The panelists do agree that a uniform national standard is to be preferred over a series of varying State and local regulations.

Mr. EMERSON. Yes.

Mr. GREEN. I don't think that the question of allocation of authority between the State and Federal Government is really a constitutional or a legal question. I think it is a political question. There are in many respects a striking analogy between the nuclear power issue and the recombinant DNA molecule issue. As you know, the question of Federal versus State and local authority in that area has become quite controversial and polarized. The great danger, I think, is that this issue of recombinant DNA molecule science and technology will become equally polarized.

If there is an absence of public confidence in Federal regulations of recombinant DNA activity as there is with respect to Federal regulation of nuclear power, you are going to have the same kind of pressures for local regulation that you have in the nuclear power area. Therefore I think it is supremely important that somehow everybody do his best to figure out a way of regulating this recombinant DNA activity that will enjoy the confidence of the public out there.

Mr. BARRON. I just wanted to make it clear that, as I say, I did agree with Professor Emerson on national standards. When I said that we should be patient with the Cambridge City Council, and more patient with them than perhaps I think people have been, that does not mean that I think they should prevail.

But I do think that the concerns that that particular controversy represents indicate that considerable respect ought to be given to the opinions of voters and other citizens and that, I think, is compatible with my idea that this ought not to be considered handoff as a legislative matter.

Mr. THORNTON. There is some distinction in the reasons for this agreement, which is, I think, apparent. Dr. Emerson believes that the primacy of Federal regulation is based at least in part upon the requirement that the regulations be by the least drastic means.

Professor Green thinks it is justified mainly on the basis of a political choice. Others perhaps on the basis—well, in part because of the nature of the activity to be regulated and the real need to move toward a worldwide solution to the problem.

Let's move now to focus upon the distinction between expression and action described by Dr. Emerson. It does appear that court decisions have not been frequent in this area and maybe have been scattered across the spectrum pretty badly as to how this constitutional right may be defined.

But it seems to me that we may be on a fresh area of public policy right here, associated with DNA, recombinant DNA research, and that the steps we take with regard to this issue may indeed become

longhand and distributing them. It means using the machinery of a printing press to disseminate the product and so forth.

Mr. THORNTON. So in your test, the running of the printing presses would not constitute action?

Mr. EMERSON. No. That would be part of an operation protected by freedom of the press. Simple experimentation is so closely related with the search for the truth that it is part of what the system was intended to protect. However, the one point which is clear to me is that when the experimentation involves serious physical injury, then the social interest lies in the action. Then it is a concern of people. At that point it seems to me the social interests should be considered, and the conduct is outside the first amendment.

Mr. BERNS. It seems to me—somewhere in the records and materials I have been reading here since Mr. McCullough asked me to be here, I ran across a statement that said scientific freedom ends at the boundary between thought and action.

I suspect from what I have read here and perhaps Mr. Green agrees with me that in this particular research that boundary is reached when the research begins. The analogy to printing presses, I am not sure how much that helps us. The condition of conducting this research requires the accumulation of *E. coli* bacteria for example.

There are problems with the collection of *E. coli* bacteria. The research simply cannot go forward without it. If the boundary is drawn indeed between thought and action, that boundary has been breeched by the activity. If that is so then the legislative power reaches it.

Mr. GREEN. I agree with Mr. Emerson that there is a very fuzzy and uncertain line between speech and action. To use his printing press analogy however, I would have no doubt that if printers' ink is carcinogenic that the operation of a printing press would be on the action side rather than the speech side.

Similarly I have no doubt that if a recombinant DNA experiment in fact makes people sick, that it is action and not speech. Now the question is trying to be less abstract about this, suppose it only probably will make people sick.

Is it speech or action? To take it a step further, suppose that it will only possibly make people sick? Is it speech or action? On this latter thing, do you start playing a numbers game to assess the degree of possibility in percentage terms? The bottom line then comes down to really who is going to decide whether there is a sufficient possibility that it will or may make people sick to warrant legislation?

I would suggest that under traditional first amendment analysis that if there is a—certainly if there is a reasonable basis for apprehension and possibly if there is only a rational basis for apprehension, that the legislative judgment will be respected by the courts.

Mr. THORNTON. Thank you. That is a very good statement. I nearly injected that some things I read make me sick. [Laughter.]

Mr. BARRON. That is not action. [Laughter.]

Mr. THORNTON. Mr. Yeager?

Mr. YEAGER. DNA research is a very fundamental thing. None of the things that Harold mentioned earlier that were being regulated such as the FDA action, AEC, human experimentation and so forth are truly fundamental research for the most part. They are mostly applications.

As Professor Emerson himself is the first to concede it has not been adopted by the court. Wherever we have had an ideal situation for the use of that approach—and I think *O'Brien* was the ideal case for it if they were going to use it—the court has backed away from it.

Here we are in an entirely different area. My own hunch—I am not sure this would be borne out—is that really the stringency of regulation should be more related to the type of research than it should be related to the stage the research is at.

I think if you use the speech-action dichotomy you are more likely to be focusing on the stage the research is at. If that is the case, then you have the kinds of things that George Wald is concerned about, that something is irreversible. I think that is a particular concern when you think that in Professor Emerson's conception, experimentation would be in the main on the speech side of the line.

I understand the reasons why he would have it on the speech side of the line because he wants to give as much protection to scientific inquiry as possible, and that experiment is the heart of the scientific method and so on.

On the other hand, if you protect that much of it and you protect it absolutely, I am not sure where regulation comes in.

Mr. THORNTON. Do you have a question, Mr. Yeager?

Mr. YEAGER. Just one more on a slightly different area. Professor Emerson is the only one who made a reference to the fifth amendment. I don't want to get into that in any detail. But with regard to protecting personal liberty, due process and so on, is there an application under the fifth amendment in this area? I was looking very briefly through some constitutional texts the other day and came across one not-too-old case in which the court upheld the authority of an individual to an education of a certain type.

I am not an expert in any of this but there seems to be a question whether it is liberty of person or liberty of action we are talking about. Is there concern with that element that we should be thinking about as well as first amendment?

Mr. EMERSON. The due process clause of the fifth amendment, of course, is a constitutional guarantee that is theoretically applicable here. In the early case that you referred to, where the court held that it was a violation of the due process clause to prohibit the teaching of foreign languages in grammar school below the eighth grade, the court considered the issue in terms of due process. They held the regulation was in effect a violation of substantive due process rather than procedural due process. That decision came before the development of the first amendment and it also came before it had been decided that the first amendment applied to the States.

So the court did not consider the first amendment. I would say that although liberty in the due process sense is involved, in most cases it would be superseded by the first amendment considerations. The first amendment has broader applications, stricter rules and normally you would first look to the first amendment for protection.

Now if you decided it was not covered by the first amendment, then substantive due process would apply. The courts, of course, have just about abandoned substantive due process in the economic area. They don't invalidate legislation on the grounds that it is unreasonable in the economic field. On the other hand, while they have never said

Mr. BARRON. Well, being confronted with it also for the first time, my reaction is including the local communities, giving them some participatory role is just at first blush a good idea.

After all, in the CAB proceedings we allow cities to participate. Of course you always have the problem that this is a big delaying factor. But I suppose if the structure is set up without too many tiers in it, maybe it is possible to include the local units and to still have it effective.

On the constitutional issue, I suppose there is more than a doubt—I agree with that—strictly—particularly with the revival of the once fading doctrine of State sovereignty. Maybe we will see some limitation on Federal legislative power in the courts.

In the final analysis, I would doubt it though. When I say there is a constitutional doubt as to preemption, I would doubt that it would be successful. In other words, I think if it were litigated, probably Federal legislation would stand just because of the kinds of considerations that moved us here this morning to think that in the final analysis it is probably better handled on the congressional level.

Mr. BERNS. May I ask that my statement which is not printed but is written be made a part of the record?

Mr. THORNTON. Without objection, your statement will be made a part of the record.

We will meet again tomorrow at 10 o'clock in room 2318 to further discuss the legal implications of the DNA molecule research issue. Our emphasis tomorrow will be on what mechanisms other than legislation might be used to effect the direction of research.

I want to thank again each of the members of our panel for a most interesting and I think reflective discussion. We are adjourned.

[Whereupon, at 12:20 p.m., the subcommittee adjourned, to reconvene at 10 a.m., Thursday, May 26, 1977.]

SCIENCE POLICY IMPLICATIONS OF DNA RECOMBINANT MOLECULE RESEARCH

THURSDAY, MAY 26, 1977

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY,
Washington, D.C.

The subcommittee met, pursuant to adjournment, at 10 a.m., in room 2318, Rayburn House Office Building, Hon. Ray Thornton (chairman of the subcommittee), presiding.

Mr. THORNTON. The hearing will come to order.

This morning we continue our hearings on the science policy implications of DNA recombinant molecule research. We are concerned with what mechanisms other than legislation might be used to guide and regulate basic research, assuming that such guidance or regulation is needed or required and more specifically with respect to DNA recombinant molecule research.

This question continues our examination of the legal implications of precedents on science research being set by this particular issue.

Our first witness this morning is Mr. Daniel Singer, attorney at law and fellow of the Institute of Society, Ethics & Life Sciences, Hastings-on-Hudson, N.Y.

Again, this morning, Mr. Singer, we would like to follow the method which we have used previously in this subcommittee of asking each of the witnesses to present his statement in summary form and then to engage in a discussion with the panel on the issues which may arise. So you are welcome and we ask you to proceed.

[A biographical sketch of Mr. Singer follows:]

Admissions

Court of Appeals of State of New York
December 3, 1956
U.S. Court of Appeals for the Third Circuit
June 3, 1957
U.S. District Court for the District of Columbia
October 21, 1957
U.S. Court of Appeals for the District of Columbia Circuit
December 6, 1957
Supreme Court of the United States
December 7, 1959

Legal Experience

1. January 1, 1965 to date:
Partner
Fried, Frank, Harris, Shriver & Kampelman
Washington, D.C.

2. July 1, 1958 to December 31, 1964:
Associate
Fried, Frank, Harris, Shriver & Kampelman
Washington, D.C.

3. July 15, 1957 to June 30, 1958:
Law Clerk to Judge George T. Washington,
U.S. Court of Appeals for the
District of Columbia Circuit

4. August 1, 1956 to July 13, 1957:
Motions Clerk to U.S. Court of Appeals for the District of Columbia Circuit. The principal function of the Motions Clerk is to act as law clerk to the three-judge panels comprising the Motions Division of the Court, and to act as additional law clerk to particular judges on special matters.

Other Legal Activities

1. October, 1965 and November, 1966:
   Volunteer attorney
   Lawyers' Committee for Civil Rights Under Law.
   Each year I spent a full month in Mississippi.
   The Committee provides free legal services to Blacks and civil rights workers in civil rights and related matters.

2. American, Federal, and District of Columbia Bar Associations:
   Various committees, including Real Property, Banking and the so-called "Miranda Project", the last involving provision of free legal counsel at police precinct stationhouses.

3. 1973 to date:
   Executive Committee
   Washington Lawyers' Committee for Civil Rights Under Law.

Non-legal Activities

1. June, 1964 (date of organization) to June, 1965:
   Director and Secretary-Treasurer
   National Committee for Tithing in Investment
   An organization seeking to encourage individual and institutional investors to allocate a portion of their real estate investment capital to open occupancy apartment houses and subdivisions.

2. June, 1963 (date of organization) to June, 1964:
   Executive Committee
   Chevy Chase Neighborhood Association
   An organization seeking to encourage fair housing practices in Northwest Washington.

Military Service

Drafted: U.S. Army, June 23, 1954
Separated: June 22, 1956 with rank of Specialist 3d Class
Honorable Discharge: June 22, 1962
Last duty station: White Sands Proving Ground, New Mexico
Duty assignment: Electronics repairman, Signal Corps
Received three letters of commendation: one for work on Information and Education Program, two for work on job.

Let me illustrate. Assume that the NIH guidelines are in place and are applicable nationwide. If Congress wishes to sustain the vigor and creativity of U.S. leadership in recombinant DNA research—without in any way compromising safety—the question to be answered in designing legislation should be: What is the least intrusive form of Federal regulation required for reasonable assurance of research safety? In my judgment, the following two minimal requirements would be adequate:

1. Certification to the Secretary of HEW by the research entity—that is, NIH, Stanford or Upjohn Co.—that, in accordance with the guidelines, an institutional biohazards committee has been established. The work of such a committee would be to review proposals for recombinant DNA research to be conducted in that institution, and to approve or disapprove proposals only upon grounds of compliance with the guidelines as to the level of required containment and the availability of such containment facilities. The composition of the biohazards committee would be spelled out generally in the guidelines.

2. Delivery to a central registry of approved proposals. This would serve a prophylactic purpose and provide data for subsequent evaluation.

For research at the P–3 level, or the level which is now designated as P–3, it might be appropriate to require in addition a 30-day delay to allow negative action by the Secretary; if no such action were timely taken, the research would be permitted to proceed. Research at the P–4 level might require affirmative approvals. Since there are likely to be only a few P–4 facilities available for such work, and because of the presently assumed higher potential risk in such work, a more thorough review would not be inappropriate.

If, however, Congress wishes to discourage recombinant DNA research—without in any way enhancing safety—Congress should mandate that a Federal bureaucracy be established to: license individual investigators, review and approve each particular research project and each modification thereof, provide for annual or periodic renewal of licenses of investigators, articulate OSHA-like protections for "whistle-blowers," authorize a corps of field policemen with rights to enter and search labs and seize and destroy products of "illegal" research, impose severe penalties for breach and so on.

To the extent either the legislation or the regulations is ambiguous, one will necessarily encourage, among other things, a whole new battery of legal specialists resident in Washington to rationalize the regulation of research, and to defend against both civil and criminal prosecutions.

In this brief time there is no need to paint the picture in Breughel-like detail. I have confidence that the wisdom of Congress is more than sufficient to prevent such a grim and unnecessary outcome.

Two further points deserve mention:

First, Congress is in the difficult position of designing legislation affording reasonable assurances of safety in the absence of any known injury arising uniquely from recombinant DNA research.

At this point in time the hazards, if any, are purely speculative. The wide acceptance of the guidelines suggests that there is general agreement that the scaling of containment to hypothetical risk is generally appropriate. With research data accumulating rapidly, it is likely that

B I O G R A P H I C A L

S K E T C H

OF W. BROWN MORTON, JR.

Born, New York, New York, November 11, 1914; married; College, University of Virginia 1932-1936 (B.S. degree); Law School, University of Virginia 1935-1938 (Ll.B degree); Admitted to the Bar, Virginia, New York and District of Columbia; Has practiced intellectual property law since September, 1938, at New York City and Washington. Practice interrupted by military service 1941-1945. My personal involvement has been concentrated in the litigation area. Since 1959, I have been a Lecturer-in-Law at the Law School of the University of Virginia, giving various courses and seminars in intellectual property. I have been a member of the American Patent Law Association (APLA) since 1950. I served on the Board of Managers from 1956-1959 and as an officer beginning 1961, becoming President in 1964. In 1956, I became a member of the House of Delegates of the American Bar Association and have been so ever since. In 1974, I was made member, and in 1975, ABA Co-chairman, of the National Conference of Lawyers and Scientists (ABA-AAAS).

Mr. Morton, we were getting started on your statement. Without objection, your statement in its entirety will be a part of the record, and I would like to ask if you could, to summarize it.

[The complete prepared statement of Mr. W. Brown Morton is as follows:]

STATEMENT OF W. BROWN MORTON, JR.

I am W. Brown Morton, Jr., a lawyer in private practice with the firm of Morton, Sutherland and Roberts at 1800 M Street, N.W., here at Washington. I received a Bachelor of Science degree in 1936 and a Bachelor of Law degree in 1938 from the University of Virginia. I have been active in the practice of patent and related law for nearly 40 years (five years in the Army in World War II excepted), here and at New York. I am a member of the Virginia, New York, and District of Columbia Bars. I have taught a one-term course in Intellectual Property Law at the Law School of the University of Virginia at Charlottesville since 1959. I have been active in bar association work, including lecturing at continuing legal education programs, for many years. I was President of the American Patent Law Association in 1964 and have since then continuously represented that association as its delegate in the House of Delegates of the American Bar Association. I am presently co-chairman for the American Bar Association of the National Conference of Lawyers and Scientists. Co-chairman with me for the American Association for the Advancement of Science is the Hon. Emilio Q. Daddario. I am sure Mim Daddario is well known to the members of the subcommittee. It is the mission of that conference to seek ways to improve the interaction of law and science, especially by improving communication and understanding between professionals in both fields.

I must stress that the testimony I shall give here and the views I express are entirely my own and in no sense represent the views of, and are in no way authorized by, any institution or organization with which I am affiliated.

The ABA House of Delegates has the admirable policy of requiring in any report submitted to it by any ABA member a disclosure of any material interest in its subject matter by reason of specific employment or representation of clients. In the spirit of this policy, I state to the subcommittee that neither I nor any firm of which I was or am a member has to my knowledge ever had any employment involving recombinant DNA nor do I or my present firm have as a client any of the seven companies stated on page 51 of the subcommittee's Supplemental Report II of December 1976 to be currently engaged in recombinant work.

I am approaching this testimony essentially on the basis suggested me by Mr. Thornton's letter of invitation of May 19.

I shall not go further into my views on the First Amendment question than to say that it clearly has an application, and I think the application of safeguarding freedom of scientific inquiry to the extent consistent with the public safety. In short, my view is that the existence of the First Amendment clearly shifts the burden of proof from the scientist in conducting research to those who would restrict his freedom. In another context, I have touched upon this in an article which I wrote about the interrelation of the First Amendment and privacy legislation. I have appended a copy of that article to my written statement. I need not point out that there is an essential paradox in the current concern with privacy, on the one hand, and freedom of information, on the other. With the fundamental political question thus posed, I do not propose to deal further but, rather, to note some specific effects of various potential applications of freedom of information requirements to the basic research process, in particular, to that process as applied to DNA recombinant molecular research.

I was struck on reading the newspapers Tuesday by the front page stories in both the Washington dailies noting that the unregulated DNA research of today has clearly now produced the probability of a dramatic improvement in the quantity and quality of insulin available for the management of diabetes. While the basic research already done today in that field may or may not have led to a patentable invention, it seems quite clear that the creation of a viable industrial procedure using that basic research will result in patentable inventions.

The patentability of inventions, of course, depends upon keeping secret their subject matter until the requisite patent applications have been prepared and filed. It is not sufficient for the Congress to look to the traditional United States patent law, with its "first to invent" approach, coupled with a one-year grace period after first publication, because the profitability of patentable inventions often depends upon the acquisition of foreign rights and in many foreign countries

at page 5 thereof. I refer to a paper that appeared in Science, vol. 146, pp. 347–355, October 16, 1964, entitled "Strong Inference."

My principal unease with the thrust of Supplemental Report No. II is in its apparent acceptance of the desirability of "public involvement" in the scientific decision-making process. Of course, "public involvement" is an undefined term, but I rather seriously doubt the value of public involvement if by that is meant anything approaching the New England town meeting concept. That concept has, as does the direct democracy of the smaller Swiss cantons, considerable appeal, but only if the subject matter on the agenda of such a meeting is subject matter which the sharing of town citizenship logically suggests to be such that all participants may have something relevant to say. My recollection drawn from general reading is that public involvement in that sense in technology decisions is likely to be wasteful, misinformed, and generally productive of delay and often of ridiculous results. The very word "Luddite," for example, makes one example of public involvement in technology implementation an acknowledged example of ridiculousness. Another can be found in the reactions of the British world to the belated adoption in that world, including the American colonies, of the Gregorian calendar to replace the Julian calendar. Riots, whether involving the smashing of labor-saving machinery or to require the return of eleven "lost" days, scarcely give much confidence in such general public involvement in technological and scientific matters. Moreover, it would seem quite clear that had there been a plebiscitary control exercised over the astronomy of Galileo and Keppler, it would have had an even more absurd effect in attempting to prolong the geocentric theory of astronomy than did the theological intervention of the Roman rota.

That is by no means to say that "public involvement" differently understood and not involving town meeting concepts of plebiscitary approaches is not desirable. In fact, I think it is conceded by all that it is essential. The thoughtful attention being given to the problem by this sub-committee is, of course, an example of public involvement at its best.

I find little that I can add to the cogency of Dr. Lederberg's discussion of this aspect of the matter appearing in Appendix 11 to Supplemental Report No. II. A very important further matter raised by Dr. Lederberg's discussion is, of course, the fact of the comparative simplicity, in terms of material resources required, of the conduct of DNA recombinant molecular research. It suggests that merely driving that research underground, either in the United States, or worse still, driving it outside the United States, is an ostrich-like maneuver only intensifying the police problem of controlling ill-advised or ill-conducted experiments. Just as with atomic energy, the cat is out of the bag, and no amount of "book burning" is going to restore mankind to its innocence, if you like, as it existed before it was found that matter could be turned into energy and before the role of DNA was revealed.

I was struck with the implications of an article entitled "The Origin of Atherosclerosis" appearing in Scientific American for February 1977, at pages 74 through 85. This article suggests that atherosclerosis, or hardening of the arteries, which is one of the most common sources of heart difficulties and is the basis for the current concern with the presence of saturated fats and cholesterol in human diet, may be the result of the operation of a mutated cell and may, therefore, be examinable and, perhaps, manageable through genetic procedures developed from recombinant DNA research. If this is so, it would indeed be a national tragedy for the conduct of the research to examine this question and develop it to be slowed down or handicapped by ill-advised regulation. We come back, therefore, to another difficulty that I have with Supplemental Report No. II.

In that report, for example, on page 25, there are references to the involvement of people identified as "ethicists" or "theologians" in reaching decisions about appropriate legislation dealing with DNA recombinant molecular research. Again, I have a serious problem of definition. I am quite unaware of what an "ethicist" is, unless it be an ethics historian, a person who has examined, and can explain for us, the customs or mores from which various particular group's ethics have from time to time evolved. If, by "ethicist," one means somebody who claims to know which ethic is right as opposed to which is wrong, I suggest that is just the sort of person we are not interested in, and should not be interested in encouraging in a pluralistic society. The ethics in which I was raised, for example, clearly hold that it is often unethical to fail to dare.

Similarly, the term "theologian" can usefully mean a person who is familiar with the history of mankind's various gods, but if it means a person able to explain and bring to bear on the regulation of DNA recombinant molecular research the word of God, I suggest the consultation of such a person is forbidden by the United States Constitution.

genes for the biosynthesis of potent toxins, e.g., botulinum or diphtheria toxin; venom from insects, snakes, etc." With deference, this seems to me a depressing sort of prohibition because I suffer from insect bite allergy and I rather feel that pursuit of recombinant DNA in this forbidden field might very well lead me to a safer and more comfortable existence than present techniques permit.

I thank you very much for this opportunity of speaking to you about a subject which is one phase, but a very important phase, of the interface between law and science.

[From District Lawyer, spring issue]

THERE IS NO RIGHT TO LIFE

(By W. Brown Morton, Jr.)

I became interested in the relationship of the computer to privacy some five or six years ago when I had a small part in an Ann Arbor program on computers and the law. My interest stemmed from my professional bias in favor of the truth and a consequent disinclination to approve tampering with the record or suppression of evidence. I submit that much that is currently being said about computerized personal data files, I.D. cards, and computer checkable identity indicia is over emotional and basically antisocial. For the more extreme privacy "nuts" I have coined a pejorative, "the right-to-be" lobby.

I recognize no such right.

On the other hand, there is a clear right to be protected against impertinent intrusion. Indeed, that seems a very good way to define the right of privacy. The proper way to protect the right is to keep to a minimum the situations in which an individual is bound to submit to an intrusion in this context, care must be taken to distinguish between actual coercion, as created by governments and government-sanctioned monopolies, and merely circumstantial impositions, as created by fortuities or comparative convenience.

The mere asking of a question to which an individual can lawfully answer. "None of your business" obviously involves no invasion of privacy, nor would the recording of that or any other answer given. The timid or the sycophantic have only themselves to blame for responding to impertinence.

When the law compels an answer to a question, that answer must be truthful and an individual should have no legal basis for complaint that the propounder of the question has used a computer to assist in verifying the answer. It is entirely proper that some questions and answers are protected by a privilege and that their disclosure and use be governed by the terms of the privilege. It is, accordingly, a very proper concern of lawyers that the questions to which the law will compel an answer be carefully defined in form and substance to eliminate the impertinent and that violations of privilege be both compensated for and punished.

But, for example, identity is a question to which many government agencies have a right to compel a completely truthful answer, this being so, the creation of an effective national identification system involves no impermissible invasion of "privacy" per se. It would in fact, be clearly in the highest public interest as an aid in combatting voter fraud, welfare fraud, illegal immigration and alien employment, and in aid of civil defense schemes for insuring the preservation of accurate vital statistics. Obviously, some national identification systems would involve more intrusion than others and lawyers have a proper concern that the system adopted be scientifically sound, practically workable, and require no more intrusion than necessary to accomplish its lawful objectives.

Congressional attention to the privacy question has been singularly unfelicitous. The Privacy Act of 1974 has produced vast bureaucratic activity as any reader of the Federal Register can attest. Mountains of paperwork have been generated, mountains more will be. Its approach is that of over administration often to the point of literal absurdity, without any evident regard for a reasonable cost-benefit ratio, and approach also manifested in recent environmental and occupational safety legislation. Some details of that act warrant comment.

Section 2(a)(2), setting forth the finding of Congress about the impact of computers on privacy, is badly phrased. What the computer does is to permit individual dossiers to be economically compiled, it does not significantly alter the potential completeness of a given dossier, it in no way affects the potential for harm from use of equivalent dossiers however compiled, and it may actually enhance the probability that a given dossier is, and can be kept, accurate.

but is silent about a $1000 unpaid account. Are the data "corrected" if the $500 error is expunged, but the $1000 error is not entered?

It is interesting to note a British point of view expressed in The Economist: (30 Oct. 76, p. 18):

Legislation in the United States has given the individual the right to know what the government's files say about him, and to correct unfair information, typically, in America, this right of examination does not yet extend to private enterprise's computers. The Swedes require the licensing of data banks, typically, in Sweden there are favours for government computers. Although the licensing board has to be consulted, the government does not have to listen to advice.

Probably, Britain should adopt the Swedish system for private enterprise computer files. It is not unduly restrictive. Most applications for licenses have been approved on the nod. But government computers, which create most of the problem cases, should be mandatorily included, and, as in the United States, there should be some provisions so that people can correct inaccurate information about themselves.

Although controls should be fairly tough, they should be applied pragmatically. The cost of changing a computer system is often high, it needs to be balanced against the degree of invasion of privacy. Existing users should be given plenty of time to amend their systems. A licence should state when the data may be used for, and who can have access. But, as circumstances change, the user should be able to come back for a quick reply if he has found another potential use and wants to adopt it.

Most lawyers are unfamiliar with the elaborate dossiers maintained by the ancient regime in pre-revolutionary 18th-century France. Only "the monarchy" could afford such manual systems, then or now. Perhaps, to paraphrase the late Huey Long. I am not wrong in regarding the coming availability of mini-computers to be one way in which every man can be a king. I should hate to have my potential for accurate and complete access to information collated and stored by me, which I hold to be a Constitutionally guaranteed freedom, impaired by a mistaken notion of "privacy."

LETTERS

Dear Editor, I would like to record a sharp dissent from the views on privacy expressed by Robert Ellis Smith. I do not consider Virginia's use of the Social Security number in order to register to vote and to serially number a driver's license anything but a common-sense step to insuring identity pending the introduction of an effective universal identifier. The technology already exists to make fingerprints machine readable and hence useful to obtain rapid verification of the recorded identity of any person whose identity is the subject of a proper inquiry. At least four important current matters of public concern require that such a universal federally-established identifier system be promptly adopted: voter fraud, welfare fraud, illegal immigration and alien employment, and civil defense identification.

W. BROWN MORTON, Jr.,
King George, Va.

Mr. MORTON. I am going to skip somewhat, having gotten over the explanation of how I came to be here.

In your invitation letter certain matters were suggested as being of interest. One I am sure is the first amendment. I think it has no more direct application than to shift the burden of proof to the persons who would seek to restrain freedom of research.

I was struck when I read the newspapers Tuesday morning last that the DNA research now being done in California had apparently produced the probability, as I read the story, of a dramatic improvement in the quantity and quality of insulin available for the management of diabetes.

It seems clear to me—I am informed by Mr. Singer that that research was carried out in accordance with NIH guidelines.

Mr. THORNTON. I believe it was in a P–3 research facility, if I am not mistaken.

Mr. MORTON. It seems clear from that to me that it would be most shortsighted to do anything to prevent the development of such an

and winter in the United States. It seems to me that such a treaty would provide all the constitutional basis necessary for Federal regulation.

Mr. THORNTON. Let me clarify a point. Your suggestion is that the commerce clause in your view does not reach the conduct of experiments in a laboratory conducted entirely within one State, absent some migration of products to or from that laboratory and absent some other basis such as supply by treaty with another country; is that correct?

Mr. MORTON. I would feel so. I suppose it is a built-in bias I have, but it would seem to me that if there is such a thing as interstate commerce, as a useful distinction, one must imagine that something remains that is intrastate and research confined to a single institution and not in fact releasing any noxious agents——

Mr. THORNTON. You know that movement of grain within a silo in an elevator has been deemed to be interstate commerce.

Mr. MORTON. And the registration of trademarks of short order restaurants located on U.S. highways has been held to be in interstate commerce too, but I still have some doubt about the soundness of those rulings.

But I have no doubt whatsoever about the treaty power in supplying an absolutely sound basis for Federal legislation to implement the treaty.

Now if we are going to have sound science applied to create sound law, it would seem to me useful for us to define our terms and in connection with some of my other interests in this matter I have attempted to do so using these definitions that science means any field of human knowledge that may be illuminated by a valid experiment—and that by law we mean—the rules of conduct which are enforced by government and which therefore include the judicial and legislative processes by which the rules are formulated and the judicial and administrative processes by which they are enforced.

That excludes from science such bodies of knowledge as are not susceptible to the experimental method and it excludes from law rules of conduct which are not enforced by government.

Incidentally, the basis for that definition I found in the work of the same John Platt, who was cited by the author of supplemental report II and if the subcommittee is not familiar with that work of Dr. Platt, it is to be found in an article entitled "Strong Inference in Science," published in Science, among other places, at volume 146 on the 16th of October 1964. It is the most careful definition of the scientific method that I am familiar with.

Now I have some difficulty with the suggestion of public involvement in the scientific decisionmaking process unless we define the term. What we are doing here today is of course public involvement in the most desirable and careful manner, and I'm sure it will be productive of public good. But the public involvement that seemed implicit in some passages at least of the report was something approaching the New England town meeting concept, and I have grave doubts about the applicability of that concept to this question.

I am reminded that when the Crown in England during George Washington's lifetime decided to change from the Julian calendar to the Gregorian calendar that riots took place. People wanted their

reached raher widely varying conclusions. There was and is nothing comparable to the NIH guidelines in that very interesting field.

I may say that I am personally hoping that DNA research will not be crippled because I would like them to come up with something that enables me to be immune to bee stings, which I am not.

I thank you.

Mr. THORNTON. Thank you very much, Mr. Morton.

Our next witnesses are Mr. Norman Latker and Mr. Rudolph J. Anderson. They have submitted prepared statements which are very comprehensive and very good. They were submitted in time for me to read through those statements yesterday before coming to the committee so that I was able to not only read them but to reread them.

I do want to commend both witnesses for the excellent presentations which are contained in these statements. It has been my privilege to have Mr. Latker, who is the patent counsel for the Department of Health, Education, and Welfare, appear before the Subcommittee on Scientific Planning and Analysis last October when we were conducting a review of the varying patent policies in different agencies and I want to again thank you for that most excellent testimony which was responsive to our inquiry.

Without objection, both of these statements will be made a part of the record and I would like to invite you to summarize those statements with particular reference to whether it is appropriate to utilize patent and license procedure, whatever it may be, as a means of controlling research in the private sector.

[The statements of Mr. Norman Latker and Mr. Randolph J. Anderson, Jr. are as follows:]

TECHNOLOGY ARISING FROM GOVERNMENT SPONSORED RESEARCH AT UNIVERSITIES AND NON-PROFIT ORGANIZATIONS TO FRUITION. THIS IS AN AREA OF VITAL INTEREST TO HEW, SINCE THE DEPARTMENT IS THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND THE SUBSTANTIAL PORTION OF ITS RESEARCH BUDGET IS DEVOTED TO THIS CATEGORY OF RESEARCH.

THE MOST OBVIOUS PROBLEM AFFECTING ULTIMATE UTILIZATION OF INNOVATIONS RESULTING FROM DHEW FUNDED RESEARCH AT UNIVERSITIES AND OTHER NON-PROFIT ORGANIZATIONS IS THE FACT THAT THESE ORGANIZATIONS DO NOT ENGAGE IN THE DIRECT DEVELOPMENT AND MANUFACTURE OF COMMERCIAL EMBODIMENTS, AND IT IS INDUSTRY WHICH MUST BRING SUCH INNOVATION TO THE MARKETPLACE.

A FUNDAMENTAL PREMISE OF DHEW PATENT POLICY AND PRACTICE IS THE UNDERSTANDING THAT INHERENT TO THE TRANSFER OF THE INNOVATIVE RESULTS OF THE RESEARCH CONDUCTED IN UNIVERSITY LABORATORIES TO INDUSTRIAL DEVELOPERS IS A DECISION ON THE PART OF THE DEVELOPER THAT THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING OFFERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS RISK INVESTMENT. OF COURSE, NOT ALL TRANSFERS OF POTENTIALLY MARKETABLE INNOVATIONS FROM SUCH LABORATORIES REQUIRE AN EXCHANGE OF INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION, BUT IT IS UNPREDICTABLE IN WHICH TRANSFERS THE

INVESTMENT HAS FALLEN SHARPLY SINCE 1960 TO AS LOW AS POSSIBLY 3.3 PERCENT.[3/] WHEN IT IS RECOGNIZED THAT COSTS TO SECOND ENTRANTS INTO THE MARKET AFTER PATENT EXPIRATION ARE A SMALL FRACTION OF THE ORIGINAL DEVELOPER'S COSTS, SINCE THE SECOND ENTRANT NEED NOT UNDERTAKE THE SAME R & D RISK, IT IS DIFFICULT TO DISAGREE WITH SCHWARTZMAN'S COMMENT THAT, "WITHOUT PATENTS THE RETURN FROM INVESTMENT IN PHARMACEUTICAL RESEARCH AND DEVELOPMENT WOULD FALL TO ZERO, AND PRIVATE COMPANIES WOULD NO LONGER ENGAGE IN RESEARCH AND DEVELOPMENT."[4/] THIS HAS BEEN ILLUSTRATED BY THE IMMEDIATE MARKET ENTRY OF COMPETITORS UPON EXPIRATION OF PATENTS ON WIDELY SOLD ANTIBIOTICS, WHERE SUCH COMPETITION DOES NOT EMERGE UNDER SIMILAR CONDITIONS IN THE AIRCRAFT OR AUTOMOTIVE INDUSTRIES WHERE COST OF DUPLICATING THE ORIGINAL DEVELOPER ARE NEARER EQUIVALENT.

THE DEPARTMENT HAS VIEWED ITS ROLE IN THE NATION'S MEDICAL RESEARCH EFFORT AS COMPLEMENTARY TO THE ACTIVITIES OF THE OTHER ELEMENTS WITHIN OUR SOCIETY, BOTH PUBLIC AND PRIVATE, THAT ALSO SUPPORT SUCH RESEARCH AND DEVELOPMENT. IT HAS SEEMED TO THE DEPARTMENT THAT THE INTERESTS OF THE AMERICAN PEOPLE ARE BEST SERVED WHEN THE VARIOUS ELEMENTS OF THIS MEDICAL RESEARCH STRUCTURE CAN INTERACT. THE MOST EFFECTIVE INTER-

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3/ IBID P. 160, SCHWARTZMAN AND HENRY G. GRABOWSKI; DUKE UNIVERSITY.

4/ IBID P. 4, SCHWARTZMAN.

LICENSING OF INDUSTRIAL DEVELOPERS. THIS HAS BEEN ACCOMPLISHED IN THE MAIN BY EXECUTION OF INSTITUTIONAL PATENT AGREEMENTS (IPA) WITH UNIVERSITIES WILLING TO CREATE AND MAINTAIN SUCH A FOCAL POINT. THE IPA PROVIDES AS AN INCENTIVE TO ESTABLISHMENT OF A PATENT FOCAL POINT, A FIRST OPTION TO OWN ALL FUTURE INVENTIONS ARISING FROM DHEW GRANT SUPPORTED RESEARCH. WE PRESENTLY HAVE 70 IPA, AND

2. ASSURANCE THAT THE INNOVATING GROUP HAS THE RIGHT TO CONVEY WHATEVER INTELLECTUAL PROPERTY RIGHTS ARE NECESSARY TO ACCOMPLISH A TRANSFER TO AN INDUSTRIAL DEVELOPER. (THIS IS ACCOMPLISHED IN THE MAIN THROUGH THE IPA HOLDERS' FIRST OPTION TO OWN HEW-FUNDED INVENTIONS AND OUR WAIVER PROGRAM, WHICH PROVIDES FOR OWNERSHIP IN PETITIONING UNIVERSITIES NOT HAVING AN IPA WHO COME FORTH WITH AN ACCEPTABLE DEVELOPMENT PROGRAM FOR AN IDENTIFIED INVENTION.)

DHEW HAS CAREFULLY CIRCUMSCRIBED THE CONDITIONS OF LICENSIN WITHIN WHICH A UNIVERSITY PATENT MANAGEMENT FOCAL POINT OR SUCCESSFUL PETITIONER CAN FUNCTION. THESE CONDITIONS HAVE

I HAVE ATTACHED TO THESE COMMENTS SOME EXAMPLES OF INVENTIONS LICENSED BY UNIVERSITIES WHICH HAVE REACHED OR ARE NEAR REACHING THE MARKETPLACE SINCE OUR 1974 SURVEY. NOTEWORTHY IS THAT THIS INCOMPLETE LISTING INVOLVES COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 80 MILLION DOLLARS. AS YOU WILL NOTE, THERE ARE A NUMBER OF PHARMACEUTICAL PRODUCTS ON THIS LIST. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT OF 1968. I WOULD CONJECTURE THAT THIS NUMBER WILL INCREASE IN SUBSEQUENT YEARS DUE TO THE OPPORTUNITY OF THE PHARMACEUTICAL INDUSTRY TO CAPITALIZE ON POSITIVE LEADS FROM THE NON-PROFIT SECTOR WHICH COULD RESULT IN REDUCTION OF THE INDUSTRY'S ESCALATING R & D COSTS BY ELIMINATING A NUMBER OF BLIND LEADS. (THE ULTIMATE SAVING WOULD BE THE DIFFERENCE BETWEEN THE 11.5 AND 24.4 MILLION DOLLARS PER SUCCESSFUL DRUG DEVELOPMENT MENTIONED PREVIOUSLY.) THE RISE IN SUCCESSFUL DEVELOPMENT BY INDUSTRY OF UNIVERSITY GENERATED INVENTIONS IS ALSO CONSIDERED SIGNIFICANT WHEN NOTING THE STEADY DECLINE IN INTRODUCTION OF NEW DRUG ENTITIES IN THE UNITED STATES FROM 65 IN 1959 TO 15 IN 1975.[6/] THIS SLIDE MIGHT ALSO BE ATTRIBUTED TO THE INCREASED COST OF DRUG DEVELOPMENT.

6/ PHARMACEUTICAL TIMES, APRIL 1976 (BASED ON DATA FROM PAUL de HAEN, INC.) AND HENRY G. GRABOWSKI, "DRUG REGULATION AND INNOVATION IN EMPIRICAL EVIDENCE AND POLICY OPTIONS," AMERICAN ENTERPRISE FOR PUBLIC POLICY RESEARCH, WASHINGTON, D. C.

BY DHEW GRANTS OR CONTRACTS WHICH THEY DID NOT CHOOSE TO MANAGE OR WERE NOT PERMITTED TO MANAGE. SINCE 1969 WE HAVE GRANTED 19 EXCLUSIVE LICENSES AND 90 NON-EXCLUSIVE LICENSES UNDER OUR PATENT PORTFOLIO. UNFORTUNATELY, WE HAVE NO STATISTICS ON THE AMOUNT OF RISK CAPITAL COMMITTED TO DEVELOPING THESE INVENTIONS TO THE MARKETPLACE, THOUGH WE BELIEVE IT TO BE SURELY MEASURED IN MILLIONS OF DOLLARS.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
DeLuca et al	U. of Wisconsin	1, 25-Dehydroxyergocalciferol for Treatment of Osteodystrophy with Kidney and Liver Dysfunction and Senile Osteodystrophy	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about $10 million.
Fox	Columbia U.	Silver Sulfadiazine used in Treatment of Burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. $5,000,000
Heidelberger	U. of Wisconsin	Use of F_3TDR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. $5,000,000 NDA expected by end of 1977.
Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, California.	On market since Feb. 1975 - Approx. $720,000
Holland	Tulane U.	Method of Reducing Intraocular Pressure in the Human Eyes (Glaucoma Treatment)	Cooper Labs., Bedford Hills, N.Y.	$2,000,000 - Development leading to DNA is in process and on schedule
Prêssman	U. of Miami	Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffman-LaRoche, Nutley, N.J.	$500,000 to $1,000,000 Clinical evaluations still in progress
Higley	Natl. Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C. R. Bard Inc., Murray Hill, N.J.	Over $1,000,000. Market introduction expected imminently.
Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. $330,000. Now on market.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Merrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides	Beckman Instruments, Fullerton, California	Being marketed since 1973.
Smith/Kozoman	Duke U.	Apparatus and Method for Rapid Harvesting of Roller Culture Supernatant Fluid	Bellco Glass, Inc. Vineland, New Jersey	$25,000 - Being marketed since June 9, 1976
Zweng	Stanford U.	Laser Photocoagulator	Coherent Radiation, Palo Alto, Cal.	Approximately $500,000 Standard tool of ophtholmologists
Sweet et al	Stanford U.	Cell Sorter	Becton-Dickinson, Rutherford, New Jersey	Approx. $200,000. Important research tool
Boyd/Macovski	Stanford U.	Computerized Axial Tomography	S.A.I. Cupertino, Cal.	Approx. $300,000. Will be marketed soon.

Mr. Chairman and members of the Committee.....
I am Rudolph J. Anderson, Jr., Associate General Counsel and Director of Patents for Merck & Co., Inc. I have been associated with Merck since 1960, with ten years of my activities related to Merck's International Division. My legal career has been primarily concerned with patent law, first with the government as a patent examiner in the U.S. Patent Office and as a Trial Attorney for the Department of Justice, and, thereafter, on the legal staff of Johnson & Johnson and Merck, both research-intensive corporations. I am presently serving on two advisory committees of the State Department: one on Transnational Enterprises and the other on International Intellectual Property.

I have been asked to comment today on the role that federal laws and regulations may serve in directing the private sector's investment in research. Obviously many laws and regulations have a direct bearing on research activities by private companies. It is appropriate, in view of my experience in the patent field, to limit my comments to the role patent-oriented laws and regulations play.

Merck is a worldwide company with production facilities in 26 countries. About 44 per cent of our $1.7 billion sales in 1976 resulted from operations abroad. Our primary business

thiazide research it discovered DIURIL, an important diuretic for the treatment of hypertension. The product was well received by the medical profession and very soon competitors were busy seeking ways to improve the novel therapy, avoid the Merck patent, and develop a product on which they might obtain proprietary rights. Today, physicians have a substantial number of excellent diuretic products from which to choose the one most appropriate for a particular patient.

The patent system also assures that society need not pay directly for this research nor make the judgments as to which research project funds should be allocated. Rather, a company each year at budget time looks at its profits from sales of products derived from previous years research and allocates part of those profits to its research laboratories in hope of further research successes and consequent future profits.

Our patent system also provides the time frame within which the total process of invention, development, product introduction and sale must be accomplished. Inventions of great benefit to society don't come into use quickly or cheaply. (I suspect there was a long expensive way from Menlo Park to the electric illumination of the halls of Congress.) However, society's enthusiastic acceptance of such break-through inventions --

part. However, I should affirm that in our industry the wisdom of the HEW patent licensing policy has been demonstrated and has resulted in significant sums of developmental research investment by companies in return for a degree of commercial exclusivity.

Legislation and regulations have also been addressed to the balancing of patent rights between the government and its contractors doing sponsored research. These involve the title vs. license policy questions and whether the government shall obtain licenses under contractor's background patents. Recognizing these to be properly matters of freedom of contract one should also note that the more onerous the background patent terms of such proposed contracts become the less likely it is that a contract will be accepted by the company most knowledgeable in the field and most likely to attain success in the research. To demonstrate my objectivity in Mr. Latker's presence, I must comment critically on the HEW's policy regarding patents in sponsored research, with HEW either taking title or deferring the determination of patent ownership until after an invention is made. The uncertainty of patent rights to the contractor deters companies from participating in such research contracts.

Of most concern to me and to most of my colleagues in industry are the proposals coming forward in the federal government relating to mandatory licensing of patents. I would like to confine my further comments to that area of public policy because in my opinion it is becoming a most significant factor in diverting research investment. Furthermore, I feel the

prices for that which solves the problem is to be certain that sales competition is not inhibited by patent monopolies.

The result is far more likely to be the opposite. For example, at the "Public Colloquium on Mandatory Patent Licensing" sponsored last January by the Energy Research and Development Administration, research directors of large and medium-sized energy companies stated that the denial of effective patent protection through mandatory licensing will significantly deter private investment in energy research. They also stated that today more energy research -- not less -- is needed if we are to meet our nation's future needs. I believe them. I think every patent counsel of every research intensive company believes them,and I think Congress should believe them.

At Merck, I participate in meetings where research management outlines individual research projects and the allocation of research funds is made. The likelihood of effective patent protection on the anticipated results of such projects can be determinative of whether a particular project will be supported. Considering that we estimate it takes a minimum of 7-10 years and an average investment of $20-$30 million to carry a promising new compound through the development,

for the patent right is self-destroying after 17 years -- through mandatory licensing in these fields must inevitably divert private sector research investment from these important needs of society.

As I mentioned at the beginning of my remarks, Merck operates under different patent systems in different countries in which we do business. It is interesting, and, frankly, a bit concerning that in many of the high technology nations housing our worldwide competitors the trend today is toward strengthening the patent laws and away from such diluting provisions as compulsory licensing.

In the United Kingdom, for example, compulsory licensing of drug patents has been in effect since 1949. In 1970, a "Committee to Examine the Patent System and Patent Law" recommended that Parliament repeal the compulsory licensing provision in Britain's patent law. The Committee found that compulsory licensing simply hadn't worked as intended, that the reduction in incentive to discover and develop new drugs far outweighed any possible savings from compulsory licensing. In March of this year the House of Lords acted on this recommendation by eliminating from a new British Patent Law compulsory licensing of drug patents, characterizing it as "an experience that has not worked". Mr. David Ennals, the Minister of Health in the Labor Government, in a speech

Mr. THORNTON. Mr. Latker.

[A biographical sketch of Mr. Latker follows:]

NORMAN LATKER

Mr. Latker, Patent Counsel for the Department of Health, Education, and Welfare, is in charge of the Patent Branch, Office of the General Counsel. This Branch is responsible for administration of the Department patent program and for legal services to the Department relating to and involving patent, inventions, and other forms of intellectual property resulting from the Department's one-billion-seven-hundred-million dollar annual research and development program. He also advises the Veterans' Administration and the Agency for International Development on an ad hoc basis.

He is currently a member of the Executive Subcommittee of the Committee on Government Patent Policy of the Federal Council for Science and Technology, and Chairman of the Subcommittee on University Patent Policy. He served on the inter-agency committee which drafted the new patent section for the Federal Procurement Regulations. He recently served on the patent Task Force advising the Commission on Government Procurement and the committee assigned to draft the ERDA patent provisions.

In the past he had been Patent Counsel to the National Institutes of Health; served on the Staff, Judge Advocate of the Air Force Systems Command, Washington, D.C.; was Assistant to the Chief Patent Advisor, Army Ordnance Tank Automotive Command, Detroit Arsenal, Warren, Michigan; and was a Patent Examiner in the United States Patent Office.

Mr. Latker was born in 1931 and raised in Chicago, Illinois, where he attended public schools through high school. He received his Bachelor of Science and J. D. in Law from the University of Illinois.

STATEMENT OF NORMAN LATKER, PATENT COUNSEL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. LATKER. Thank you, Mr. Chairman.

I think that the use of of patents in order to regulate might be a somewhat spotty type of means of control, if control is considered to be necessary.

I think the emphasis in my statement is really along the lines of permitting the university innovating group to own their own inventions and make their own interfaces with the industrial sector through the licensing of their inventive products.

It would appear to me that to utilize university licensing to control industry probably would not be successful and would probably also create an undue burden, if that expectation were placed upon the university sector where I think most DNA research is now being done. There was some discussion within the Department of Health, Education, and Welfare along the line of the question you asked and I think the consensus was in line with what I have just said. So I believe that most agree that the patent mechanism would not be an appropriate means of attempting to control DNA research, if that control is considered to be necessary.

Mr. THORNTON. It would seem to me that among the difficulties might be that the use of impediments to patenting might well discourage all research without regard to an assessment of its potential risk or its potential benefits but would rather be tying an equal burden or handicap on all research without making any determination as to the merits of that particular program. Would you agree with that view?

Mr. LATKER. Yes.

JULY 1977

Rudolph J. Anderson, Jr.
Ridge Road, Gladstone, New Jersey

Curriculum Vitae

GENERAL INFORMATION

Born April 15, 1924, Brooklyn, New York; married, eight children. Resident of New Jersey since 1951; resident of Peapack-Gladstone, New Jersey for 10 years.

CAREER SUMMARY

Associate General Counsel and Director of Patents, Merck & Co., Inc., health products corporation headquartered in Rahway, New Jersey. A member of Merck's Patent Department since 1960; formerly of Johnson & Johnson, where he first served in the Law Department and later became Director of Industrial Products and Assistant to the President, Permacel Division. Began career as a Patent Examiner in the U.S. Patent Office and Trial Attorney for the Department of Justice.

Former Township Committeeman, Scotch Plains, New Jersey
Former Chairman of the Planning Board, Boro of Peapack and Gladstone, New Jersey

EDUCATIONAL RECORD

J.D. - 1951 - Georgetown Law School
B.S. (Chemical Engineering) - 1947 - University of Notre Dame
B.S. (Naval Science) - 1945 - University of Notre Dame

MEMBERSHIPS AND AFFILIATIONS

American Bar Association (Chairman, PTC Committee 106 - Inventors; newly appointed Chairman of PTC Committee 101 - Patent Law Revision; former Chairman of PTC Committee 102 - International Patent Treaties & Laws)
New Jersey Bar Association
Virginia Bar Association
District of Columbia Bar Association
State Department Advisory Committee on Transnational Enterprises
U.S. Council of International Chamber of Commerce
Association of Corporate Patent Counsels
Pacific Industrial Property Association
American Patent Law Association
New Jersey Patent Law Association
New York Patent Law Association

high development costs from concept to marketing for such inventions.

The patent life provides the profit levels for sufficient periods of time to assure an adequate return after the development costs have been met.

In recent years we have seen enacted, or proposed, legislation and regulations that make significant changes in these fundamental elements of our system, and I truly believe these changes will have a major impact on the private sector's research investment planning. The laws and regulations fall in three major categories. In one category are those relative to the management, that is, licensing, by the Federal Government of patent rights obtained under federally funded research: either research performed by the Federal Government itself or by Government contractors.

I think Mr. Latker's paper and comments on the subject, your bill, and the committee's activities here need no additional comment from me. I compliment the HEW patent policy, as the basic Federal rules that have been successful in translating early concepts from research laboratories and universities into products that benefit the public.

Mr. Latker's statement has attached to it the success stories of how they were able to draw from industry millions upon millions of dollars of development funds.

Mr. THORNTON. There can be no doubt that there has been a substantial improvement in the dissemination of scientific information into the marketplace and an accrual of benefits resulting from a positive approach by HEW. I think that point is well made; however, I believe you mention in your paper that the uncertainties attached to whether a particular invention will be patentable and will accrue to the benefit of the inventor does cause some concern.

Mr. ANDERSON. Yes, sir. I admire the licensing policy of HEW but have some concern with the patent policy of HEW when they sponsor research by commercial organizations. That policy provides that HEW will retain title to inventions made by a private contractor, or that HEW will wait until the invention is made and identified and then they will decide whether to take title or not.

I have known Mr. Latker for many years and I just want to demonstrate to him my objectivity with a compliment on one side and a complaint on the other.

Mr. THORNTON. You did note that the bill I have introduced does provide for title to remain with the inventor.

Mr. ANDERSON. Yes, sir, with appropriate protection to the public. I certainly compliment the bill and the drafters of the bill who I assume are sitting close to you on the dais. I think the bill is very well done.

Mr. THORNTON. I think it might be appropriate for us to include, as a matter of fact, some of the comments with regard to patent policy which are here in future hearings which we may have on the bill or to ask you to supply additional information at that time.

I do thank you for that.

Mr. ANDERSON. I would be happy to. I would like to mention the deep concern that we have on an issue that may arise in connection with your proposed legislation or in the debates that will occur on bills relating to DNA research and research in other fields. That

It is particularly a problem in the fine chemical field for products such as prescription drugs, herbicides, pesticides and the like where the specter of compulsory licensing is particularly discouraging to innovators, the research and development cost in time and money is very high, but it costs competitors very little to mimic the commercial product of the innovator once the research and development has been completed.

It should be appreciated that the value of such a high technology product is not the cost of the components or its production and marketing. The chemical, once proven to have beneficial utility and developed to assure safety, may cost only a few cents a unit to produce. But if the chemical cures a disease, makes a farm more productive, or satisfies some environmental need, its true value is determined by what the products does for its purchaser.

It is this, the major component of product value, that patent rights are designed to protect. Another way you can look at it, frankly, is if you buy a Joan Sutherland recording of "Norma," you are paying for the sound that comes from the record, not the plastic that is in the record.

If innovators cannot reasonably expect profits to recover research and development, investment in both winners and losers—they will not—and indeed they could not for very long—continue the research which leads to the products society wants and needs.

The early destruction of patent rights—because the patent right is self-destroying after 17 years—through mandatory licensing must inevitably divert private sector research and investment from these important needs of society.

In my paper, Mr. Thornton, I also mentioned that in Britain right now—after 30 years of compulsory patent licensing—the House of Lords has eliminated the concept of compulsory licensing of drug patents from the new British patent law and the Labor Government announced in April they were satisfied there was no need for compulsory licensing.

I don't want to take any more of your time, Mr. Thornton, but I do think your committee ought to address itself to this issue most seriously, not only to your present legislation on DNA research, but I also think, for the benefit of the public, your committee must address itself to all of these proposals for compulsory licensing that are showing up in each research-oriented piece of legislation on the Hill.

Mr. THORNTON. I thank you for that observation and I want to insure you that it will be the intention of the subcommittee to schedule later in this session, if at all possible, further hearings on patent policies themselves in order to develop additional information on the subjects which you have mentioned.

Of course, our immediate concern is, as you know, with the issue of the means which may be employed, assuming that regulation of recombinant DNA molecule research is deemed to be necessary and the effect of restrictions on patents granted on research which does not meet NIH standards. We feel it is necessary to address the question of whether this kind of inhibition is an appropriate legislative or regulatory method of controlling research in the private sector.

Mr. ANDERSON. Mr. Thornton, I would make a small bet with you that the well-thought-out treatment of that subject matter and the de-

DAVID J. NEWBURGER

Assistant Professor of Law
School of Law
Washington University
St. Louis, Missouri 63130

Personal

Place of Birth:	Bowling Green, Ohio
Date of Birth:	July 15, 1943
Health:	Polio victim. With the use of two crutches and one leg brace, mobility restored to near normal. Ability for sustained and intensive work impaired. Health otherwise excellent.
Marital Status:	Married
Children	Girl, born July 11, 1969

Education Background

A.B. Government, Oberlin College, Oberlin, Ohio 1965.

J.D. Case Western Reserve University, School of Law, Cleveland, Ohio, 1969. Standing: Second out of 126. Order of Coif; Editor-in-Chief, Case Western Reserve Law Review.

Work Experience

July, 1972-Present	Assistant Professor of Law, Washington University. Courses include Corporations, Regulated Industries, Securities Regulation, Legal Process (a first year, part technique and part jurisprudence course). Consultant: Committee for Environmental Information, Utility Consumers Council of Missouri, Inc.
February, 1971-July 1972	Deputy Director for Policy Planning and Special Assistant to the Director, Department of Commerce, State of Ohio, 366 East Broad Street, Columbus, Ohio 43215.
July, 1969-February, 1971	Associate, Arnold & Porter, 1229 Nineteenth Street, N.W., Washington, D.C.

Publications

"Securities Act of 1933 -- Rule Modification -- The No-Sale Rule and the Privilege to Avoid Regulation," 19 Case Western Reserve Law Review 1148 (1969).

STATEMENT OF PROF. DAVID J. NEWBURGER, SCHOOL OF LAW, WASHINGTON UNIVERSITY, ST. LOUIS, MO.

Mr. NEWBURGER. Thank you very much, Representative Thornton. I have delivered to the committee today a statement which I would appreciate being included in the record.

Mr. THORNTON. Your statement will be made a part of the record in full.

[The complete statement of Professor Newburger follows:]

Admittedly, these appear a random collection, but they represent concerns, crucial for writing an effective regulation but often ignored in much of the important literature. In the second part of these remarks, I examine some important features of possible regulations to allow but restrict research using the recombinant DNA technology. The final part notes some implications of the more extreme proposals, both those to allow largely unfettered research using that technology and those to proscribe such research.

I. A Menu of Perspectives

For all practical purposes, no regulatory program successfully achieves the goals spawning its enactment. Any regulation of research using recombinant DNA technology which Congress may adopt has two competing goals: (1) To encourage free and active research and (2) to eliminate risks of danger to workers and the public from such research. A new regulation with those goals is likewise unlikely to be completely successful. That, however, does not dictate that Congress, and this Subcommittee, should concede failure and forego efforts to regulate. Rather, it suggests that the subcommittee judge proposed regulations according to their propensity to achieve legislative purposes and to their potential counterproductivity for such goals. Then the subcommittee must compare the potential for success and counterproductivity of proposed regulations with that of other proposals and the status quo.

What are characteristics of a regulation most likely to avoid dangers and least likely to discourage safe research using recombinant DNA technology? Three principles may assist finding the

I refer both to flexibility of standards and of enforcement devices. An enacted standard is less flexible than one adopted as an administrative rule, and that in turn is less flexible than an administrative order. The law or rule are more inflexible because they are adopted without reference to their effect on each particular case; they speak with a broad brush. Such standards likely have gaps allowing conduct intended by Congress to be prohibited and prohibiting that intended to be allowed.

Impediments to imposing more inflexible enforcement devices, such as criminal laws, are less telling for those more flexible, such as summary license suspension authority or cease and desist order power. Hence, their application is less likely to occur for several reasons. Criminal prosecution connotes, socially, very significant wrong doing. Thus, administrators quite properly in my opinion, often are loathe to use that enforcement tool against people not conforming to regulatory standards but not appearing to be truly "bad actors." Further, the presence in the enforcement process of prosecutors, grand juries, judges, and juries in addition to administrators increases the possibility that the conduct, determined by the administrator to be violative, ultimately will be ruled acceptable. Finally and related, the criminal justice system contains presumptions which preclude criminal conviction on facts sufficient for a cease and desist order, if permitted by the regulation.

Some considerations, however, limit the desirability of flexible regulations. An administrator with very flexible tools has broad power to apply the regulation either consistently or inconsistently with Congressional policy. While unlikely that

technology. We know very little about the actual dangers, although we guess that they might be great. Therefore, to set inflexible standards for conduct today would be folly. The probability is great that the standards set today based upon incomplete information gathered in the early part of what promises to be a long investigation-- will be sometimes more and sometimes less stringent than ultimately appears appropriate.

II. The Scenario of Permitting Some Research Using Recombinant DNA Technology

To allow research using recombinant DNA technology in order to realize foretold beneficial innovations but to limit it to avoid unacceptable worker and public health and safety risks requires a complicated pattern of regulation. Since the regulation should permit all research not taking "unacceptable risks," the initial question for designing a regulation is how to determine what risks are unacceptable. Such is not amenable to precise determination; Congress is left with two alternatives. First, it may proscribe identifiable conduct which has a high likelihood of involving the unacceptable risks. Prohibiting unqualified investigators, or investigators using unqualified facilities, from engaging in this research fits this alternative. Second, it may decide what risks are acceptable or identify an individual or group in whom it delegates that responsibility. Such an alternative ranges from Congress' relying on judgments of each qualified individual investigator working in his or her own laboratory, to its relying on some form of peer review and oversight authority, to its relying on decisions of a Federal Administrator, to its enacting standards, and combinations thereof. Both of

distributes to the unqualified will reduce the number yet further. Indeed, the outward limits of these control techniques can be very severe. However, if too severe, the "halo" effect, noted above, of precluding related but acceptable conduct will grow.

A simple prohibition of those unqualified from engaging in research using recombinant DNA technology will keep the vast bulk of people from this activity. But, the problem becomes more difficult when drawing a line between those which the regulation considers qualified and those not quite. Administratively, it is easiest to enforce that distinction by requiring all who wish to engage in the research to obtain a license. The administrator can then review the qualifications and conduct of each.

Such a requirement, however, has the deleterious effect of increasing the cost of the research activity, because the investigators, including those unquestionably qualified, must obtain the license and suffer the delays and bureaucratic impositions attendant therewith. Further, given that research using recombinant DNA technology should only be conducted in facilities that are qualified for that purpose, it might be possible to substitute licensing laboratories for licensing individual investigators. In such a scenario, all investigators would have to be prohibited from engaging in this research outside licensed laboratories, but that seems to be a necessary standard in all events. Then, laboratories would be licensed and investigators would not be.

Such a plan has the advantage of reducing impositions on investigators. However, it poses the problem that unqualified investigators might be employed in licensed laboratories. Such difficulty might be ameliorated by authorizing the licensing

lation and the other does not. (3) A list of specific research activities can be drawn in which each item can be allocated to one or the other category. Finally, (4) such a list cannot feasibly be exhaustive.

Recalling the concern that the regulation not foster uncertainty, a twofold approach for identifying activity required to be licensed might work best: First, the regulation would list those research activities required to be licensed and those not. Second, it would provide a conceptual definition for those activities not required to be licensed. Such an approach allows investigators certainty about conduct not required to be licensed when that is possible, and allows independent exercise of judgment when the case cannot be predetermined. Variations can be selected to fine tune the balance between regulation and independence of the investigator. For example, one might give the administrator the power to develop the list activities not required to be licensed or to expand the list based on information learned after enactment.

III. Other Scenarios

In the previous part, I developed some of the implications of one type of regulation possible. Potential variations are legion. But, two proposals represent extremes beyond which the licensing alternative reaches. Congress might determine not to legislate on the subject of this research at all. On the other hand, it might enact an outright prohibition of such research. Each possibility suggests observations deserving comment.

One of the reasons apparent for not legislating in the area is to protect the independence of scientific investigation. Such

regulation, designed to ensure risks are minimized within the bounds possible and in light of the research that will occur.

Conclusion

In sum, I believe that we have a tendency to overestimate the value of regulations enacted. Notwithstanding, I believe that regulations can be designed which reduce risks of public and worker hazards significantly and which do not unduly impinge on innovative research. To do so, however, is a complex task requiring a thorough understanding of this field of research, of regulation of other activities, and of the workings of administrative agencies.

Thank you for this opportunity to express my views.

Inflexible regulations tend to be unsuccessful in two senses: One, they tend to be overbroad and apply to conduct we didn't want to restrict. Two, they tend to be underbroad and skip past some conduct we are concerned about. Under those circumstances, allowing administrative agencies the flexiblility of rulemaking authority, order making authority, and the flexibility of enforcement devices like cease-and desist-orders powers as well as criminal penalties, creates a greater possibility that the regulation adopted will be useful.

On the other hand, and the third observation I want to make, the great difficulty with flexible regulations is that they create uncertainty in the people who are regulated, and uncertainty is one of the worst things for innovation. Mr. Anderson alluded to that already when he suggested that the possibility of having to license patented discoveries has the effect of discouraging people from engaging in research, not knowing what they are going to be able to do with the product of the research they are engaged in.

And in that respect I suppose one of the important goals for this subcommittee and Congress is to settle as quickly and as firmly as reasonably possible what regulations will be so that scientists and industry will know with greatest possible certainty the implications of their engaging in this area of research.

On the subject of the regulation changing people's conduct, I want to point out a very important concept that I might refer to as the halo effect. If you push the regulation too far it may discourage certain kinds of wanted conduct. For example, if we have a regulation that would make it a very serious penalty to engage in a certain kind of conduct and if indeed there was a high probability that that penalty would be enforced, not only will we discourage the conduct that we intend; also, we will discourage acceptable conduct that resembles the unwanted conduct, because people will be concerned the possibility that the activity, though not now deemed unwanted, subsequently may be. If we get involved in that sort of situation in the area of basic scientific research, we risk excluding large areas of wanted activity.

With that background. permit me to discuss briefly the question of licensing recombinant DNA research. First of all, I understand there has been some discussion of whether there is a difference between "licensing" and "certification." As far as I can tell from the law dictionaries and other sources I looked at before I came to this session, there is not—certainly, I have not been able to figure one out. I think they have different connotations in ordinary usage but I don't think those carry through to any legal implication.

Using the word "licensing" to mean that broad range of activity, I believe you might allow some wanted research and restrict some unwanted by means of a licensing process. You might consider doing that if there are some people who should not engage in recombinant DNA research, for example, people who do not have sophisticated laboratories or people who do not have the training and competence to handle that kind of research.

To achieve that, it seems to me we can do three things in this area. Prohibit people who are defined to be unqualified from engaging in that kind of conduct. Require licenses of people who are to engage in that kind of conduct and look at each one to see whether he is qualified.

And, third, introduce a monopolization of some factor in the re-

Mr. NEWBURGER. In the first instance, let me say that the regulation of broker dealers seems to me to be a much more extensive regulation than should be necessary in this instance. That industry is very, very tightly regulated, to regulate so tightly basic research that would present some very serious problems.

But, the idea of allowing a self-regulatory organization to participate in the regulation seems to me to be a very interesting one under the circumstances, largely because when we are evaluating the dangers that are involved—these are scientific questions and it is that peer group which has, in some respects, the best hope of being able to reach intelligent decisions.

On the other hand, as you no doubt recall, the SEC has the authority to direct the NASD to promulgate rules and it can overrule the decisions of the NASD and its enforcement. That ultimate authority probably needs to be retained for whatever agency would regulate here.

Mr. THORNTON. A number of questions which have been dealt with relating in part to that is whether there should be, assuming regulation is needed, a preemption at the Federal level and whether there should be a procedure whereby variances might be resolved by a review group at the Federal level in the event of a particular exception or incident being appropriate to a local community. Mr. Singer raised his hand on that, and I would like to ask both of you to give your comments.

Mr. SINGER. Mr. Thornton, on the issue of preemption I think our recent experiences in Cambridge and Ann Arbor and Princeton and on the west coast suggest that this is an area, namely, the regulation of recombinant DNA, in which preemption is singularly appropriate.

Harvard and MIT escaped, if you will, the downside of nonpreemption for a variety of reasons, one of which was the exquisite good sense and good judgment of the Cambridge experimentation review board. It seems to me that however at risk universities may be to episodic conflict on traditional lines, our colleagues here and others who would represent the pharmaceutical industry may be unable to prevail as did Harvard and MIT in circumstances where they are less than the most important employer in the community. And it would seem to me that in either instance were there no Federal preemption the community of people most directly affected, namely, the scientific investigators, constitute a singularly mobile community within the universities at any rate and perhaps somewhat less mobile within the industrial community. And they would simply move were they afflicted with, say, the views of Mayor Vellucci. Had those views prevailed in Cambridge there would have been an even greater exodus than there has been in fact under the mere threat proposed by Mayor Vellucci against investigators continuing with their research under conditions which are widely regarded as safe or reasonably safe.

Mr. THORNTON. Thank you, Mr. Singer.

Mr. Newburger?

Mr. NEWBURGER. I think that the question becomes whether the State or local regulation is going to serve the goals that are intended. It seems to me quite clear, as Mr. Singer points out, that State and local activity raises uncertainty very substantially for the research-

such committees, one may be able to achieve both goals simultaneously, namely, that the community within which the work is being conducted feels that it is not a total irrelevancy with respect to the work that is going on in its backyard and yet at the same time the work is enabled to proceed pursuant to what are widely regarded as appropriate safety standards.

Mr. THORNTON. Thank you.

Mr. NEWBURGER. Representative Thornton, there is an additional thought, I think, that grows out of Mr. Anderson's comment that I want to make sure is clear. One question presented when deciding who should make a decision is what the incentives of a proposed decision-maker are.

For example, the question, I believe, has been raised in the literature of whether NIH is really an appropriate authority to be regulating this kind of research in view of the fact that one of its chief goals is to promote the research. My concern is that we be aware that the fact that the Federal Government is reviewing proposed research does not necessarily mean that that reviewer will be applying the health and safety goals of this proposed regulation. That depends upon how the reviewing agency perceives its responsibilities.

Mr. THORNTON. I think it might be useful to pose a question by attempting to summarize very briefly an analysis which was presented to us yesterday and on previous days of the hearings and then ask for some comments.

First of all, we are dealing with a subject which can be divided into at least two and possibly more than that very distinct enterprises. One is scientific research and experimentation. And, of course, there may be a distinction there between expression and action in the laboratory. But contrasted with that element of scientific inquiry which may involve active experimentation, comes the question of commercialization, the use of the research activity in the private sector. And they question whether the same means of regulation should be applied to both of these distinct operations or might it be useful to analyze each of these areas of conduct and try to determine whether regulation is needed and, if so, what that regulation should be for each type.

Now the reason I focused upon that distinction first is because the issue of using the patent policies of the United States as a regulator may apply differently to the two different sectors. It might have a different impact upon commercialization than upon the basic research activity.

Another distinction which I think needs to be considered is that there is a great difference between research which is funded by the U.S. Government. I think it goes without much question that the Government has the right to determine within constitutional boundaries how that research money may be spent. And another area of research which is funded and carried forward by the private sector, including universities and non-Federal enterprises of the private business community.

All of these things give us an exceedingly complex problem to address. One problem associated with it—and, Mr. Latker, your presentation reminded me of this—is that we do expend a lot of Federal money for research and one of your objectives has been to flow the benefits of those large expenditures of money back out into the private

analogize it in my own mind, Mr. Thornton, to the role of the bank examiner. The bank examiner examines all the accounts of the bank but unless he finds that there is a criminal or other economically dangerous situation, it does not come out what he saw.

There seems to me to be no reason why the regulators of research who find out what is going on in order to find out whether there is a hazard that they should stop, should have to reveal what they have seen if the Congress provides that that information is not subject to the Freedom of Information Act.

Mr. THORNTON. Let me ask each of you to give me your thoughts with regard to whether there should be a provision of law, assuming that legislation does move forward in the area of recombinant DNA research, which would say that no person who does not adhere to a set of guidelines promulgated for DNA research and be able to demonstrate that the research activity was carried forward in accordance with those guidelines shall be eligible for patent protection for any discovery that might result from that research.

Mr. MORTON. If I may speak to that, abstractly, such a provision of the patent law could be envisaged. The original statute of monopolies in Great Britain rewarded stealing ideas from the French the same as it did for thinking them up, but I doubt it would be easy to do as a practical matter in the framework of patent laws which exist today, because as you outlined your thought or concept——

Mr. THORNTON. My question.

Mr. MORTON [continuing]. You immediately call to my attention the fact that it would be a violation of treaty obligations of the United States.

Mr. LATKER. First I would agree with Mr. Morton in that such a provision would only be effective in the United States, if it could be administered. I think I have some difficulty understanding how it could be administered other than asking for a certification from the patent applicant at the time of filing.

At this point I only can envision that the U.S. Patent Office could administer that type of provision. I am sure there would be some reluctance on their part to pick up any investigatory kind of responsibility. I do not think I have too much difficulty in perceiving a situation where they would be satisfied with certification with the possibility of penalty if that certification was determined to be incorrect at some later date.

Mr. MORTON. If I may observe, Mr. Chairman, the trend is very strongly to pay little or no attention to the how a discovery comes about and look solely to the what, so much so that in the recent patent cooperation treaty it may be possible at some time in the future not to even identify the inventors of an invention because all you identify is the proprietors.

It is very difficult sometimes in industrial research—I am sure Mr. Anderson will bear me out—to pinpoint the exact individuals who have made the patentable contribution. Therefore, the trend is, coming from Europe in particular, to have patents granted only to proprietors and let inventors who have been defrauded go to civil court if they have been and then they can recover.

Mr. THORNTON. Mr. Anderson?

Obviously, this research is a global problem. So it may be that by means of a patent device it would give us an extra-territorial handle which is otherwise unavailable. If that is not the case, it does seem that it is one of those extremely inflexible devices that ought to be used to bear only if we are faced with tremendous noncompliance that we just don't see any other way to bring them into compliance.

Mr. THORNTON. Thank you.

Mr. Singer?

Mr. SINGER. I had heard your earlier questions not as distinguishing between research being conducted in scholarly institutions and what I would call for this morning nonscholarly institutions [laughter] industrial laboratories, but rather the question of safety as it relates to the research and development process as distinct from the kinds of considerations that might be relevant to decisions of whether or not a particular product or technique ought to be made available publicly.

Mr. THORNTON. If I may just go forward for a moment to illustrate. It would seem to me to be quite a different question to determine within a laboratory that a bacteria could be developed, or, not only to determine it, but actually to develop a bacteria which was capable of producing nitrogen and living symbiotically with the roots of cereal grains. That is one question.

It is quite a different question as to whether to produce those bacteria in large quantities and sell them commercially to farmers so they can apply them to the roots of their crops. I think there is a distinction between the two enterprises not on the basis of who is doing the research——

Mr. NEWBURGER. Representative Thornton, for the record, I definitely agree with that. When you introduce the quantum leap in the size of production, that definitely raises different questions about the kind of regulation.

Mr. THORNTON. I didn't mean to take away your comments, Mr. Singer. I just wanted to agree.

Mr. SINGER. I would like to follow on if I might in precisely the framework of agricultural revolution, if you will. First, I think that at the present time the quantity limits on production is directed specifically toward the safety of the undertaking of the research itself.

But it seems to me—I have said this many times in other contexts—that decisions whether or not to introduce into commerce, to permit the introduction and sale of an altered corn seed; namely, a corn seed that acts like a string bean, is a very different question than questions regarding the safety of the development of that idea. The question with regard to the introduction of the fancy corn, if you will, relates to costs and benefits in a very large social sense. Those are issues, in my judgment, which, first of all, may be decided quite differently in this country that they are in India, for instance, and in both cases quite reasonably.

Although we talk about energy shortages, we are not flat on our back because of energy shortages, and to continue to produce nitrogen-rich fertilizers, for instance, in this country would not bankrupt us.

Likewise, we seem somehow to have mastered the technique of producing an awful lot of corn under present seed conditions and we might, as a society, quite reasonably decide that whatever our efforts

of their end items in this country. They would be filing patent applications in the United States.

So, therefore, if you had a requirement for such certification to validate the patent, then you would have some control over the use of the guidelines in France and Germany. I do not know whether it would be productive. I cannot suggest that it would. Again, I'm certain that it would have holes in it, because all inventions are just not patented.

Mr. THORNTON. Mr. Singer, do you have a comment?

Mr. SINGER. It seems to me that we are making certain very implicit and probably very wrong assumptions about the conduct of people. I think Mr. Anderson was quite correct when he said that people are really going to abide by the guidelines, just set them out there and we'll abide by them. I think that has certainly been the experience within the scientific community, albeit under a very peculiar kind of threat, namely, withdrawal of funding.

But even that work being conducted without Federal funds, insofar as anyone can tell, being done in compliance—let us say university research other than with Federal funds, with Cancer Society funds or something like that, it is being done in accordance with the guidelines. The scholarly publications in the relevant field are one by one adopting policies that require as part of the publication—and as you recognize, publication is the name of the game of the scientist—that there be a statement with respect to recombinant DNA research not only that the research was done in accordance with the guidelines but spelling out the level of containment used for the particular types of experiments being reported upon.

If one looks also in contrast to the stockbroker analogy at who it is that is likely to be hurt by a violation of the guidelines, at least in the stockbroker case his violations of the broker-dealer rules may get him in trouble but in the process he in a sense—what we are talking about is stealing other people's money in that instance. The investigators, whether they be industrial or academic laboratories, are talking about themselves, the first victims, if you will, are very likely to be the investigators themselves and the immediate laboratory workers and other people within the cartilege of the laboratory.

Their incentives to comply with what other people have thought to be reasonably safe suggestions are, I suggest, different and I would like to think higher than those kinds of risks that stockbrokers run with other people's money and therefore might appropriately give rise to different expectations as to the conduct of the individual most immediately affected.

Mr. NEWBURGER. I think there really needs to be a couple of comments on what Mr. Singer suggests to you. First of all, the imposition of a regulation may involve some cost for the person subject to the regulation. But, in large part, those are the costs that are already implicit in the NIH guidelines. Thus, for a person already subject to the guidelines, the additional cost resulting from enacting regulation is not very significant, except to the extent that the regulation has the halo effects that I referred to earlier.

Therefore, the introduction of regulation, with attendant enforcement techniques is not a major concern of the person who will comply

Mr. ANDERSON. I really don't know what I said that drew the comment I may lack confidence in our scientists. I would ratify Mr. Singer's point. I do think the facilities of our laboratories and the required new investment in facilities will be relatively less of a problem for us. I also think that the people involved in this research may come out of the universities and look toward industrial research.

Mr. THORNTON. Mr. Latker?

Mr. LATKER. I am beginning to enjoy your question more and more as the debate goes on because it keeps refining itself. I just have to make a last statement about the statement I made before.

I suggested there would be holes, and as I hear the debate going on it seems to me that in the industrial sector side, denied the possibility of patent protection, because they did not abide by the guidelines, I think you would have very few holes since I don't believe they would give up the idea of patent protection just to avoid an investment containment. I think all the holes would be on the nonprofit side because there the incentive for filing patent applications is not as strong as it is on the industrial side. Putting this all together, it could be suggested that regulating legislation could be avoided by a threat of denial of patent protection on the industrial side if the guidelines weren't observed and mandating the guidelines on the university side as a condition of Government funding.

Mr. SINGER. One more brief comment on the same point. The people who work in industrial laboratories have a lot broader experience dealing with dangerous pathogens in laboratories. And if you look back to where the containment standards are developed, they are developed from experience in dealing with dangerous pathogens at CDC in Atlanta. Then have those scientists who are most actively involved in doing active recombinant research—let us say that while there is tremendous progress in many universities in dealing with dangerous pathogens, it is not the same people who are the molecular geneticists, if you will, of the next decade who have already got that body of experience and habit pattern, you have to look at the microbiologists I think to learn how they do work with pathogens.

So the facilities, if you will, probably already exist in industrial laboratories. I just am not hung up on the question of compliance with announced guidelines. That, also, I think, colors my own view about how rigorous or elaborate a system of regulation is likely to be required to give us reasonably high levels of confidence that the guidelines are in fact being observed.

Mr. THORNTON. All reasonable men would certainly comply with reasonable guidelines. I think the concern is whether all men are reasonable.

Mr. SINGER. Clearly, they are not.

Mr. NEWBURGER. And whether all guidelines are reasonable.

Mr. SINGER. That is less relevant.

Mr. THORNTON. I want to thank you gentlemen for a most stimulating discussion.

I would like to ask if we might submit questions to you for clarification or amplification of the areas we have covered this morning and those areas which were mentioned in your prepared papers.

Are each of you willing to respond to such questions?

[Affirmative responses.]

[Mr. Newburger submitted the following additional information:]

problem related to serendipitous discoveries (one that did not come up at the hearing on May 26) emphasizes that point. We can anticipate that a patentable discovery using recombinant DNA technology will be made in circumstances in which the investigator had not intended nor anticipated being in the area of regulated activity. For example, as we know, research is presently underway to verify the standards set by the NIH guidelines. By definition, part of that research is outside those standards. The product of a serendipitous discovery during the course of that research might not be amenable to patent if the proposal were adopted, even though we might excuse an investigator from meeting regulatory standards because of the serendipity of the discovery.

This problem might be mitigated by making very definite and limited the area of conduct subject to the precondition for obtaining a patent. However, the more that definition is narrowed or made explicit, the more likely that conduct which should be subject to the precondition will be allowed to escape. Thus the likelihood that this type of regulation will not cover all conduct intended would increase.

The other major disadvantages of this proposal fall into two categories: (1) The proposal would not extend to all research using this technology, even in the United States. (2) The device necessitates an added layer of bureaucracy.

The precondition on patents will not cover all research for two reasons. Some researchers, particularly those in academic settings, may be uninterested in the commercial value of their discoveries. Other investigators may choose to avoid review for having followed the standards by relying on trade secrets, rather than patents, to ensure the commercial advantage of their discoveries. To avoid this disadvantage, one requires a more direct form of regulation--such as licenses, prohibitions, and government control of restriction enzymes--to ensure all domestic research is covered.

There seems no way around this last disadvantage I perceive: The existence of the patent precondition requires an administrative staff to implement it. Perhaps the matter could be simplified, for example, by requiring the Secretary of Health, Education and Welfare to certify what discoveries have been made in compliance with the NIH guidelines and to require patent applicants to obtain such certification as the condition to obtaining the patent. But, some added cost and effort is involved.

An underlying principle also raises doubts about the proposal. Indirect mechanisms complicate regulations. Preconditioning patent approval upon compliance with the guidelines indirectly does what can be achieved by licensing and prohibiting in the United States and by treaty agreeing to

license and prohibit abroad. Such may be justified to achieve goals not otherwise attainable. But, using more direct solutions may help make compliance easier and more predictable and may contribute to better relations with other nations of the world.

I hope that these additional thoughts are useful for you. The question is fascinating because the advantages and disadvantages of the proposal are great.

Very truly yours,

David J. Newburger

David J. Newburger
Assistant Professor of Law

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Mr. THORNTON. Thank you for your testimony.
[Whereupon, at 12:25 p.m., the subcommittee was adjourned.]

WASHINGTON UNIVERSITY

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SCHOOL OF LAW

June 9, 1977

The Honorable Ray Thornton, Chairman
Subcommittee on Science, Research and Technology
Committee on Science and Technology
United States House of Representatives
Washington, DC 20515

Dear Representative Thornton:

On May 26, at the request of your staff, I appeared before your Subcommittee on a panel discussing proposed regulations of research using recombinant DNA technology.

During the course of that hearing, we discussed the possibility that patents for discoveries resulting from research using recombinant DNA technology be withheld from investigators who do not demonstrate that they engaged in that research in a manner consistent with the NIH guidelines. I have reviewed that proposal since that hearing and write to send you more collected thoughts on the subject.

At the hearing, we did not develop a thorough analysis of the advantages and disadvantages of the proposal. As a result, I think that both advantages were understated and some disadvantages overlooked. Permit me to summarize some positive and negative attributes of the proposal.

On the positive side, the proposal would present a tremendous incentive for investigators--and particularly investigators looking to the commercial utility of their work--to comply with the NIH guidelines. Further, the regulation would constrain the manner in which foreign investigators engage in research using recombinant DNA technology. While many of those investigators would not be subject to federal agency implementation of the NIH guidelines, they would be forced to comply with the guidelines if they are to market their discoveries under patent in the United States. This, in turn, has the added advantage of eliminating incentives to export domestic research. This is similar to the advantage of which Mr. Singer spoke on behalf of the federal government preempting regulation of this sort of research: shopping for different research locations has a lower payoff.

On the minus side, disadvantages also loom large. For example, the proposal is to adopt an enforcement device of the very inflexible nature that I worried about in my paper. A

anyway. What the enforcement technique is addressed to is the possibility that somebody won't comply.

Second, we must recognize that the incentives for the scientific community are oriented toward achieving successful research, but the goals of the regulations we are considering to insure public safety and worker safety as well as to achieve successful research.

Thus, I am very troubled whenever somebody suggests a regulation is necessary but assumes it will be complied with and, therefore, asserts that effective enforcement mechanisms can be foregone. In such circumstances, it is often difficult to ascertain whether everybody is complying with the regulation. If not given the absence of enforcement devices, we have not achieved our goal.

Mr. THORNTON. Yes, Mr. Anderson.

Mr. ANDERSON. I really can't let the comment by this panel on successful research go by. Mr. Singer made the point before that successful research may be measured in some part in the research community by the number of publications. His point was that publication is the name of the game. If it is interesting enough to make the journal, then it is "successful" research.

I think you would find that, if we were doing research, the name for successful research would be whether there is a product to be sold at a profit at the end of a research project. I think those are two different definitions of success and I think they call for two different regulatory concepts.

Mr. THORNTON. I agree.

Mr. Singer, do you have a comment?

Mr. SINGER. Just one kind of response to the last two remarks. I am astonished to find myself having a good bit more confidence in even the industrial scientist than apparently the Assistant General Counsel or Patent Counsel or Director of Patents has. This is a unique position for me. It seems that one other way to look at this when one talks about the cost of compliance, the cost of compliance with the regulations or the guidelines in terms of the percentage of an academic grant which must be devoted to upgrading laboratories, or if you will, determining to do a different kind of experiment, are I would suggest substantially greater in cash than are the costs of upgrading an industrial facility to a P–3 or perhaps even P–4 status.

My own feeling is that the question of physical containment and physical safety is going to be handled more quickly and more reliably and with less pain financially within the industrial community than within the academic community. The academic community is going to have to spend what for it is a tremendous amount of money to come up to P–3 levels of containment. And I suggest they would abandon any attempt to reach P–4 levels.

I think that is simply likely. It is going to be NIH or specific NIH funding of regional centers, which is likely to be the rule for P–4 experiments.

But for any particular department of biochemistry or biology even at major universities to undertake the building of such a facility it seems to me in these days is just simply unlikely. Unlikely sufficiently expresses my view on that, but the cost and reward potential for very highly upgraded facilities within an industrial laboratory, it seems to me, are minimal in comparison to the $150 million per year that is spent only at Merck as part of its research budget.

were going to be to enhance our agricultural productivity, if any, they ought to be directed in other areas.

On the other hand, the Indians who are in a real way very hungry and very short on the kinds of quantities of energy needed to produce nitrogen fertilizers might say it is worth anything to us to get hold of that fancy seed and to go ahead and plant it all over the place, because that is the only hope for physical survival. Those considerations, that totting up of pluses and minuses seems to me an exquisitely political type of decision which is not made on the grounds of safety at all. We are well beyond the safety considerations. It seems to me that the safety considerations as such focus almost entirely, certainly at this time, on the manner in which research and development activities go forward.

And the other question is the question relating to the exploitation of the technology, whether it be in an agricultural area or whether it be in an area that we will very loosely and regretfully call human genetic engineering, they are just miles apart.

And as I said in my statement, I would urge——

Mr. THORNTON. I think it is important to make clear that human genetic engineering is not necessarily associated with working on a corn seed or something like that.

Mr. SINGER. No; but I think that one could make the case just kind of as an aside that those who do the work with respect to the insertion of the so-called Nif genes, the nitrogene fixation genes, into that seed, are going to learn a tremendous amount about how to insert other kinds of information into other kinds of genes because at the level you are working, that stuff all looks very similar.

But I would urge that in attempting to develop a legislative framework that focuses on safety that we not be distracted or diverted from that effort by considerations which we must in a sense learn much more about and experience much more and think about rather than questions of, if you will, mere safety.

Mr. THORNTON. Mr. Latker?

Mr. LATKER. I just would like to amplify a little further on your question about the patent control idea that you suggested. The Patent Office—I do not know what state this is in at this point, but I think they have committed themselves to the idea of accelerated processing of DNA patent applications. And, as I recall, part of that accelerated processing required a statement or certification that the DNA guidelines were being honored.

Given the thought that patent protection in the area, at least in the pharmaceutical area, is extremely important, it would seem that the Patent Office in a way has somewhat committed themselves to the idea that certification may be a means of insuring that the guidelines are being adhered to.

One other point is——

Mr. THORNTON. What I am asking is, is that a suitable means?

Mr. LATKER. As I think I said before, I think it will have holes in it. I would add one other thing, the suggestion seems to me the only mechanism that I have heard of that would have some extraterritorial effect because you would have the French and the Germans coming into the U.S. Patent Office if they wanted protection for the delivery

Mr. ANDERSON. I think, getting back to your basic question of the use of the patent system in this fashion, we in the United States believe we would be able to adhere to the guidelines. I am an optimist: I think that when you are finished the guidelines will be such that everybody will have a degree of certainty which is indeed important. You will protect the confidentiality to eliminate the loss of any patent rights worldwide. But your question ignores the fact that the research will be conducted throughout the world and the law will be applicable to U.S. patents.

When I say that we could live within it, I am sure the Merck organization could adjust to abide by the U.S. rules for U.S. patentability. I think my colleagues in Bayer in Leverkusen, Germany might say "Who is this Representative Thornton who is telling me how to do my research?" They expect to obtain patents on their research. We cannot ignore the territoriality aspect of patents when considering this whole problem.

Interestingly enough, I am sure that you saw that Senator Kennedy visited Hoffman LaRoche in New Jersey who have had a facility—I don't know whether it is P–3 or P–4——

Mr. THORNTON. P–3, I think.

Mr. ANDERSON. It certainly is true that if it were to become uncomfortable for Hoffman LaRoche to conduct research in New Jersey such research could not be instituted over the weekend in Switzerland. The mobility point made for it is very valid. Our laws can cover our own problems and our own geographic areas of concern, but they will not effect from the patent standpoint the mobility aspect of this problem. It is an international problem.

Mr. THORNTON. Mr. Newburger?

Mr. NEWBURGER. Let me back up a little further to the question which you ask, whether the regulations should distinguish between basic science university type research and industrial research. It seems the concern we are faced with is not who is doing what, but that some dangerous organisms might be released into the world. That is the problem. And whether those happen to be university spawned or industrially spawned does not make a great deal of difference. The concern is that they be there.

The distinction is important, however, from the point of view of what enforcement devices will be included in the regulation in order to achieve that basic goal. And the question of denying the patent for noncompliance with the guidelines is nothing more than one of several alternative enforcement devices that are available.

It seems to me that that kind of enforcement device is of the very inflexible type that I was referring to in my remarks. If so, it ought to be a very suspect kind of proposal if there are alternative devices that can achieve the same goal. Before Mr. Anderson responded to your question, that is where I would have ended this comment. One thing that he said, however, stimulates an additional thought: It may be possible that by using the patent mechanism—and I am not a patent expert so I don't know for certain—we can reduce the possibility that these organisms will flow over from the Canadian or Mexican border into the United States. Further, that there may be other mechanisms available to do so.

sector. As a public policy matter, certainly that would seem to me to be commendable. Do you have any other thoughts or suggestions or ideas as to how benefits can flow out into the private sector from privately funded research?

Mr. LATKER. I think I have sort of isolated myself into the use of patents as an incenive to move those results into the private sector recognizing the sensitivity, especially of the pharmaceutical industry, to the need for patent protection.

But if I could divert for a moment, I particularly enjoyed Professor Newburger's discussion on certainty. I think the HEW policy and what I believe to be successful dissemination of the results of HEW-sponsored research at universities is based upon the concept of certainty. I think prior to 1968 that certainty just did not exist. And again the thrust of my comments is along the lines of what Mr. Newburger is suggesting, to make sure that that certainty continues to exist in all areas of science research.

I would also talk about disincentives or uncertainty for a moment. I do not think we have picked up Mr. Morton's comment about the uncertainty created by the Freedom of Information Act and the Federal Advisory Committee Act as it might impact on DNA research. Here I would have to suggest that I am speaking for myself since the administration bill in the area of DNA came forth without any kind of science information clause in it clearly leaving disposition of such information under FOIA and FACA. I think Mr. Morton correctly points out that FOIA and FACA create a great deal of uncertainty as to proprietary rights and if that uncertainty is permitted to remain, participation in the research and technology transfer will both be adversely affected.

Mr. THORNTON. Would you say it is costly to fail to provide patent protection in some of these areas of medical research and development?

Mr. LATKER. I personally am certain that that is the case. I feel that the failure to provide for patent protection and utilize it where necessary—and sometimes patents merely can be used to nonexclusively license industries or parties of interest—but in those situations where a great deal of risk capital is necessary and an exclusive position is the only way that that risk capital is going to emerge, then the failure to provide for patent protection—and that could be cut off, as Mr. Morton suggested, by premature disclosure under FOIA or FACA, then what you have done is basically frustrated the research in the first instance, whether it is publicly or privately funded.

Mr. THORNTON. As Mr. Morton stated in his prepared text the concern is that unless some means is found to allow the research effort to remain confidentially treated until it is time to seek patent protection, unless that is preserved somehow, you have a very difficult situation as far as both private and federally funded research.

I don't want to overly summarize that, but would you like to expand on that?

Mr. MORTON. Yes, Mr. Chairman. It seems to me there is no inherent conflict between the regulation that may be necessary and disclosure prevention if the Government regulatory agency accepts that disclosure for the purpose of the regulation only and on a confidential basis, unless, of course, their investigation shows a great hazard. I

ers. As a result, it definitely will have the effect, at least in particular cases, of discouraging research. On the other hand, the difficulty with preempting is that the Federal Government thereby takes total responsibility for having found the correct answer for balancing the policy goals presented. The great experiment of the State laboratories is forgone. That heavy responsibility should be assumed by Congress, it seems to me, only under two circumstances—if Congress is quite assured that the States and local governments are unnecessary or if it concludes that the damage that they will do far outweighs the benefits that they might deliver. How you weigh that, again, it seems to me is a difficult public policy question that perhaps, with my mortarboard on, is not something I should jump into.

Mr. THORNTON. Yes, sir, Mr. Anderson.

Mr. ANDERSON. If I may—and I don't pretend to be the expert on DNA research—I think the question of preemption will in many ways depend upon that which you are ultimately intending to regulate. I say this particularly with respect to private sector activities. If, in fact, there are objective standards of safety in laboratories, I think very few people in the private sector will be concerned with the cost of complying. I think all of us would be planning to do the research using the best facilities possible.

In the private sector, the question that comes into play is who is going to make the judgment of whether or not some particular research project should be carried forward. I think when you are talking about Government-sponsored research you have a situation where a petition is filed with the Government for financial support of that research and, as a prerequisite, the nature of the research to be conducted is filed in the application. The judgment of whether that research should go forward or not go forward is made not only from the safety standpoint under the new regulations, but also under some judgment as to whether that research is worthy of Federal funding.

Private sector research does not have that element and I think this will be the critical point you will have to identify in determining the nature of regulations. The judgment as to which project goes forward is properly a responsibility of the Federal Government funding it under legislation or regulation. The funding will follow depending upon those regulations. Certainly that has to preempt the judgment of Kalamazoo, Mich. city council or that of Rahway, N.J. There just is not the ability to make those kinds of scientific worth judgments in local communities, if that becomes the nature of regulation.

Mr. SINGER. Let me make an additional comment with respect to preemption in the hope that we can isolate some of the issues within preemption. The setting of national guidelines for recombinant DNA research set up certain standards. It seems to me not inappropriate to focus on—and those guidelines require the establishment in each institution of a facility where such research is being conducted of a biohazards committee which undertakes today the responsibility for determining the adequacy of the facility in which the research is to be conducted and which also, I believe today, under the existing guidelines has the responsibility for determining the appropriate level of containment required with respect to particular research proposals.

If one is able so to structure the membership of the local biohazards committee so as to make likely some noninstitutional local input on

search, such as perhaps a Federal monopolization of the manufacture for sale of restriction enzymes in order to decrease the opportunity for the amateur scientist to get into this research. This would not unduly impose on qualified scientists who, being licensed, would be permitted to purchase restriction enzymes and who, in any event, are likely to be willing and able to make their own supply.

Outright prohibitions and monopolization of restriction enzymes are, in a sense, the easy part. The hard part is distinguishing—in the licensing area—between those who are qualified and those not quite. That problem, obviously the most difficult, has generated a number of suggestions. I shall not go into them all.

I do suggest in my prepared remarks, some thoughts about licensing laboratories as opposed to individual investigators. I think the question of licensing laboratories is a rather thorny one, because at least at my university laboratories do not have separate corporate existences. Exactly who the laboratory to be licensed is would be difficult to decide. Perhaps that is something that can be worked out. If so, licensing laboratories would be an attractive alternative because it would limit impositions on scientists by eliminating the requirement that every single scientist engaged in this research obtain a license.

I think, however, if the judgment is made to license laboratories, that the subcommittee ought to consider the regulation of securities broker dealers under the Securities Exchange Act of 1934 because there the SEC was given the interesting power to license the broker-dealer and to exercise some control over persons associated with the broker-dealer. The person associated does not require a license in the sense that the broker-dealer does, but if he engages in bad acts, he can be told to cease and desist. In fact, he can be barred from associating with broker-dealers. So it seems to me that some kind of a combination of regulation licensing laboratories but also allowing the enforcement agency to move against particular bad actors, rather than restricting the agency only to granting or denying licenses, might well maybe move in the direction of flexibility and avoid some of the extreme halo effects of regulation.

In conclusion, permit an example to show why I think that is true. If Merck laboratories has a license to engage in this research and one of its people turned out to be a bad actor, it would be a terrible thing to take the license away from Merck Laboratories. But if that bad actor can be removed from the scene, the bad activity is controlled. Thus, the good work of the laboratory could go forward and the bad actor could be taken out of the system.

Thank you very much for your attention.

Mr. THORNTON. Thank you very much, Mr. Newburger. I wonder if in citing to us the example of the SEC regulation of broker-dealers you were also alluding to the fact that in that particular regulatory scheme there is established a peer group, the National Association of Securities Dealers, which enforces those regulations such as hot stock rules and others by holding hearings, conducting inquiries and proposing punishments to be applied, whether it may be a suspension or a fine or whatever.

Are you suggesting that that parallel should be followed entirely or only insofar as you outlined it?

Mr. NEWBURGER. In light of that, I only want to summarize some thoughts I suggest in that statement.

First, however, by way of background, together with two colleagues at Washington University, I have engaged in two projects for the National Science Foundation examining the question of regulation and innovation. Specifically, we conducted a state of the art review of the influence of regulation on innovation in the chemical and allied products industries. And we are just completing a study of that question related to the production of ammonia.

Give that background and that I come to this discussion with expertise on the impact that regulation has on innovation rather than on issues of recombinant DNA research, I thought it might be useful to present a brief framework within which to analyze proposed regulations.

There are two deep policy problems related to recombinant DNA research. One is the possibility that public and worker health and safety may be endangered by this kind of research. The other is that research and innovation, historically essential to this country's achievements, might be curtailed unduly by regulation.

When you put those two policy goals together, obviously, you have a conflict, and no regulation written is going to solve perfectly both goals. On the other hand, choosing no regulation will not necessarily improve the situation.

Under those circumstances, it seems to me that the question is not whether a given regulation will succeed in the ultimate goal but whether a given regulation will succeed in the ultimate goal but whether a proposed regulation will have a greater propensity to succeed in the ultimate goal than other proposed regulations none at all.

That being so, the problem becomes how to evaluate a new regulation. Now I want to be clear that I cannot help you decide just how daugerous recombinant DNA research is. That is a matter on which scientists will give you guidance, but a matter of public policy that ultimately you in the Congress will have to work out. But let us, just for the sake of further discussion, assume that there is danger in this research which justifies some regulation. I think, then, three observations about regulations might help you think through how to design the best regulation in this instance.

First, I suggest that we ought not think of regulations as telling us exactly what conduct will occur. All regulations do is to create a propensity for certain conduct to occur, and indeed, sometimes a poorly drawn regulation spawns conduct quite different from that desired.

So, we should think about a proposed regulation from the point of view of how it will be received in the situation in which it will apply and try to second guess how those regulated will modify their conduct in response to the regulation's enactment.

In connection with that, and this is a fact which Congress has recognized in a broad range of other areas of regulation, is my second point—regulations which are inflexible tend to be unsuccessful for achieving their underlying purpose. By inflexible, I refer both to inflexible standards, such as those set by statute rather than administrative agency, and to inflexible enforcement tools, such as criminal penalties.

a decision might be justified on the grounds that independence of scientists has been one of the major cornerstones for America's technological growth. No doubt, it has. However, science is controlled in several respects by the Federal Government today, and Congress does have the power to so regulate. Thus, a decision not to regulate this research is not neutral. Instead it suggests that Congress has determined it preferable to allow that the risks of this research be assessed by individual investigators in order that they not be hamstrung in their research pursuits. Also, it suggests that Congress has determined that legislation and an administrative agency will not better protect the worker or the public from the risks of this research than will individual investigators.

On the alternative of enacting an outright prohibition of research using recombinant DNA technology, one must observe that such an effort may be impossible. Efforts to use domestic regulation withaworldwide impact, such as denying patents for foreign researchers not complying with American standards of care, would not preclude this research. Absolute prohibition in the United States will not eliminate the dangers if their risk is global and the research is not prohibited everywhere. Of course, Congress might still prohibit the research in order to establish this Nation's good faith in a broader effort to secure worldwide prohibition. Also, it might do so in order to reduce the quantity of the research conducted and thereby reduce the statistical probability that the dangers will materialize. On the other hand, however, it might decide that a worldwide prohibition goal is unrealistic and therefore adopt a significantly different regimen of

agency to suspend or revoke laboratory licenses of laboratories employing unqualified investigators. Also the licensure system might borrow a concept from the Securities Exchange Act of 1934, giving the licensing agency some power over individual employees in licensed laboratories. For example, the agency might be given the authority to order a specific individual or group to cease and desist specific activity or to order that they be barred from employment by a licensed laboratory for a time specified or permanently. Such enforcement tools have the added attraction of improving the administrator's effectiveness. Without them, he or she might be confined to revoking the license of a laboratory in which individuals are out of compliance, and in specific circumstances, that might be too great a penalty given the violation.

Licensing laboratories and not individuals is not without its disadvantages. Identifying the laboratory as an entity subject to regulation may not be simple, especially since most are not separate corporations. Ascertaining lines of responsibility among investigators within the laboratory may also be difficult. Other problems may exist. Presumably, when working out details of a proposal these can be overcome.

To my knowledge, one more significant problem with licensing remains: What conduct is to be made subject to the license requirement? At the risk of delving into a scientific question beyond my ken, I understand that research using the recombinant DNA technology has the following characteristics: (1) It is reasonably easy to distinguish from other research. (2) There are two categories of research using that technology: one justifies the regu-

these alternatives appear likely candidates for regulating the use of recombinant DNA technology.

Publicizing the prohibition of unqualified individuals--or of individuals working in unqualified laboratories--from engaging in this research will deter much of the unwanted conduct. Likewise, providing both flexible and severe enforcement tools against violators will deter some or all intentional bad actors from violating the prohibition.

Nevertheless, the prohibition will be ineffective with respect to those who do not know about it and those not deterred by it. If Congress determines that a significant number may fit these categories, it may search for ways to deprive unqualified individuals and laboratories of the capability to undertake the research. For example, in the instant case, it may set limits on those who may manufacture, sell, buy, or possess restriction enzymes. Such a solution by itself would be insufficient to prohibit research by the unqualified since these enzymes can be manufactured in private laboratories. On the other hand, manufacture is difficult, and thus the more unqualified would be effectively disabled from engaging in this research.

The combination of the two control techniques would work to reduce to a very small number the group of unqualified individuals and individuals in unqualified laboratories who might engage in this research. The number can be reduced even more by increasing the severity and variety of possible penalties imposed. Introducing penalties for the qualified manufacturer or seller who

administrators will be unwilling to comport with Congressional policy, they may be unable. When setting standards, they may not have the advantage of collegial debate or broad public interest which may arise by right of the matter's being in Congress. They may not have sufficient staff and budget to perform professionally assigned responsibility. Thus, the quality of their decisions may be poor.

Also, greater flexibility in a regulation may enhance uncertainty about acceptable conduct, and uncertainty can negatively affect innovation. That is the third principle I bring to your attention. We have already noted the "halo" effect that extreme penalties can have, discouraging conduct not meant to be prohibited. Uncertainty about standards, and the predictability of their enforcement, can have a similar effect. Indeed, it may be greater. The halo caused by extreme penalties only extended to activity not clearly distinguishable from prohibited conduct. Since uncertainty may spread over much more conduct than that likely to be prohibited, the halo will similarly extend. Uncertainty can discourage people for numerous reasons. Businesses will avoid incurring substantial R & D or capital expenses to enter a field from which they may ultimately be prohibited. Basic research investigators will not wish to commit their careers to research they ultimately will have to cease before completion.

Having already seen the case favoring flexible regulation, one cannot conclude, however, that regulations ought to be made inflexible in order to ensure certainty. A balance must be drawn. And, that balance must take into account the peculiarly difficult problem posed for regulation of research using recombinant DNA

answer.

First, while regulations purport to dictate conduct, they do not necessarily have that result. Indeed, sometimes they dictate unintended conduct. For example, consider a regulation which prohibits conduct. If it is not well known or is well known but not enforced, it will not be very successful at forestalling the prohibited conduct. On the other hand, if enforced by imposition of severe penalties for violation, it may not only preclude the prohibited conduct but may also preclude related conduct. This will occur if the regulated party fears that the enforcing authority will extend the prohibition--and, therefore, the severe penalty--to the related conduct. Thus, when prohibiting conduct, Congress must consider (1) the tolerability of the unwanted conduct's occurring occasionally, (2) the success with which prohibited conduct can be distinguished from that not prohibited, and (3) the importance of having the nonprohibited conduct continue. Depending upon those judgments, Congress can select penalties of various severity. Also, it can reduce the possibility of inadvertent violation. For example, it can insert a licensing requirement to increase awareness of the regulation among people involved in the area of conduct. Or, under some circumstances, it can restrict access to factors necessary to engage in the conduct, thus disabling those prohibited from the conduct from so engaging.

My second principle is this: Generally speaking, the more flexible the tools available to the administrator, the more likely he or she will be able to apply the regulation in a manner consistent with Congressional purposes. By flexible tools,

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Before the

Subcommittee on Science, Research & Technology

of the

House Committee on Science and Technology

Statement of David J. Newburger, Assistant Professor of Law,
Washington University, St. Louis, Missouri

Mr. Chairman and members of the subcommittee, I am David J. Newburger, an assistant professor of law at Washington University in St. Louis, Missouri. I appreciate this opportunity to discuss some effects that regulation will have for research using recombinant DNA technology. My background, and therefore the focus of my discussion, lies not with that technology, but with the influence of regulation on innovation. Two colleagues, Christopher T. Hill, now on the staff of the Office of Technology Assessment, and Edward Greenberg, a professor of Economics at Washington University, and I conducted "A State of the Art Review of the Effects of Regulation on Technological Innovation in the Chemical and Allied Products Industries" for the National Science Foundation and submitted a report under that title in February 1975. Since then, we three have pursued that research and will soon submit a final report to the National Science Foundation of another study, entitled "The Influence of Regulation and Input Costs on Process Innovation: A Case Study of Ammonia Production."

In my remarks today, I first bring to your attention several aspects of the interrelation between regulation and innovation.

Publications, Cont'd.

"Materials on Regulated Industries," (Tentative ed. 1977) (mimeo).

"A Preliminary Assessment of the Costs and Benefits of Disclosure of Chemical Industrial Information Acquired Pursuant to Health, Safety, and Environmental Regulation," with E. Greenberg, C. T. Hill, W. P. Darby and A. D. Norman. Report to the U.S. Council on Environmental Quality by Washington University Technology Associates, 65 pp., October 21, 1976.

"The Effects of Regulation on Technological Innovation in the Chemical and Allied Products Industries," with E. Greenberg, C. T. Hill, G. R. Whitaker, et al. Report to the National Science Foundation Office of R & D Assessment, Vol. I, Executive Summary, 16 pp.; Vol. II, The State of the Art, 205 pp.; Vol. III, Abstracts and Literature List, 500 pp.; February, 1975. Available from NTIS.

"TheInfluence of Regulation and Input Costs on Process Innovation: Interim Report: Innovation in Ammonia Production," with E. Greenberg, C. T. Hill, T. M. Helscher, W. V. Killoran, A. D. Norman, and H. A. Zar. Report to National Foundation, Division of Policy Research and Analysis, 183 pp.; July 1976.

"The Influence of Regulation and Input Costs on Process Innovation: A Case Study of the Ammonia Industry," with E. Greenberg and C. T. Hill, 266 p.; June 1977.

"Electric Power: Who Pays for Expansion?," Environment Magazine, June/July 1977, at 50.

Statement before the House Subcommittee on Science, Research and Technology May 26, 1977.

gree of control that will ultimately prevail from this committee will be challenged on the floor with an amendment for compulsory licensing of the results of such research in the private sector.

Mr. THORNTON. I appreciate that observation.

Our next panelist is Prof. David J. Newburger, professor of law at Washington University, St. Louis, Mo. Professor Newburger is a gentleman who comes from my part of the country. It is a real pleasure to welcome you to our subcommittee and we would like to ask you to proceed.

[A biographical sketch of Mr. Newburger follows:]

issue is the fundamental concept of compulsory licensing of patents.

Mr. THORNTON. As a matter of fact, we are operating perhaps on a mirror image of the same policy considerations which were involved in attempting to develop a uniform patent policy. If patent policies should be uniform and a means of encouraging the dissemination of scientific information to the general public, if that is a policy consideration, it would seem to me that that varies considerably from the concept of using patent policies as a means of regulating or selecting which particular kind of research should move forward. I think it might be useful to draw clearly that distinction between the two possible uses of patent policy.

Mr. ANDERSON. I do believe that when you get down, Mr. Thornton, to matters of compulsory licensing, the dialog is founded on one or two basic concepts, often not expressed. The first is that society's needs in some areas of technology are so great that no industrial organization should have "monopoly" rights in the field.

It is implied, though seldom stated, that profitseeking enterprises and free competition in the marketplace simply cannot be trusted to satisfy public needs.

In the other concept, it is suggested and sometimes directly stated, that the social value of some products—and we lump drugs in that area—is so great that private suppliers must be denied what are called excess profits. Thus the patent system should be used to provide a mechanism for price control.

In the first area, the public needs area, we have seen compulsory licensing of patents inserted in the Clean Air Act and proposed for the Energy Research and Development Act. There must be a half dozen bills before this Congress proposing it for prescription drugs.

There is no doubt that environmental protection, abundant energy, and good health care are socially desirable goals, and it is understandable that society would like to achieve these goals as soon as possible and at reasonable cost. People argue that one way to insure reasonable cost, rapid results, and low prices is to be sure that competition is not inhibited by patent monopolies.

The result is far more likely to be the opposite. For example, at the public colloquim on mandatory patent licensing sponsored by ERDA in January, I heard research directors of large- and medium-sized energy companies state that the denial of effective patent protection through compulstory licensing in energy acts would significantly deter private investment in energy research.

I heard them say that they think more energy research is needed, not less, if we are to meet our Nation's needs. I believe them. I am certain every patent counsel of every research intensive company believes them and I think Congress should believe them.

At Merck I participate in meetings where research management outlines individual research projects and the allocation of research funds is made. The likelihood of effective patent protection on the anticipated results of the projects can determine whether a particular project will be supported. Considering that we estimate it takes a minimum of 7 to 10 years and an average investment of $20 to $30 million to carry a promising new compound through the development process, you cannot blame us for being concerned about patents.

STATEMENT OF RUDOLPH J. ANDERSON, JR., ASSOCIATE GENERAL COUNSEL AND DIRECTOR OF PATENTS, MERCK & CO., INC.

Mr. ANDERSON. Yes, Mr. Thornton.

I think it is quite appropriate that I pick up on the point of Mr. Latker's statement about this risk capital question, because I have tried to devote my paper to the point that Government regulations and laws can have a very direct steering effect on private research investment.

I am pleased to speak to this point since the Merck organization is putting about $150 million per year into research, primarily research that is health-oriented: animal health, human health and environmental health. Most of what we sell we have invented and developed in our own laboratories.

This investment in research causes us to have strong feelings about the patent system. We believe that one of the basic elements that the patent system is designed to accomplish, namely, to protect freedom of competition, is fundamental to our industrial system and we think that freedom of competition includes the ability to do research on equal terms.

We also believe that the reward for effective competition—the proverbial carrot—is the profitable sale of new products that the companies manufacture. And we think that the greater the value of inventions we and others make, the greater the value to society, and the more likely that the new product will be sold profitably. We do not deny the concept of profitability being a measure of success in any area.

We think the patent system as it exists today is quite well designed to protect and encourage competition. For example, Merck did the first research on thiazide diuretics and we made a scientific breakthrough resulting on our new product. Diuril, for the treatment of hypertension. The product was very well received and our competitors were soon seeking ways to improve this novel therapy to avoid the Merck patent, and to develop a product on which they could obtain proprietary rights. They were successful. Today, doctors have a number of products to treat the major problems of hypertension.

Our patent system also assures that society need not pay directly for this research, nor does society have to make judgments as to which research projects should be funded.

I think it is important that we recognize that a company each year at budget time looks at its profits on sales of products from previous years' research and allocates part of those profits to its research laboratories in hope of further research successes and consequent future profits.

Our patent system also provides a time frame within which the total process of innovation, development, product introduction and sale must be accomplished. As I indicated in the paper, inventions of great benefit to society don't come cheaply and they don't come quickly. The route from Menlo Park to the illumination of the Halls of Congress was long and expensive.

But the enthusiastic acceptance by society of scientific breakthroughs—computers and copy machines and lifesaving drugs and the like—does bring profit levels which are adequate to cover the

Mr. THORNTON. Similarly, I think the thrust of your statement, as I read it, was that it is a most difficult thing to move innovations from the laboratory into use in the society where they afford benefits to the members of society. Your suggestion, as I understand it, is that patent policy be designed so as to make it possible for innovations which are developed and demonstrated scientifically to be beneficial to be moved into the marketplace. Is that it?

Mr. LATKER. Exactly. I think I keep making this statement over and over and I think I made it the last time I was before you, Mr. Chairman, and that is, that there is not a keen enough recognition of the difficulty of transfer from the nonprofit sector to the profit sector. It is a complex and trying situation and I have this feeling that the lay person has the idea that the mere announcement in the newspapers of the existence of an idea means that that idea will ultimately reach fruition within a few months.

The Department experience has been otherwise and, again, if I had to get down to the botton line of my presentation, it would be that the Department feels that we need to encourage the incentive of filing patents and the use of patents in order to aid this transfer from the nonprofit sector to the profit sector and any legislation that would impede that would be counterproductive.

Mr. THORNTON. I believe that you mentioned that during the years from 1962 to 1968 there was a virtual boycott.

Mr. LATKER. That is right. Anybody who has read the 1968 GAO report I think would be taken aback by the fact that here on one side of the ledger you have the Federal Government putting millions of dollars into research, coming up with what appeared to be some very useful and significant ideas but the industrial sector basically refusing to aid in the collaborative development of those ideas because the additional risk capital that they had to place into the fruition of those ideas was not protected by patents.

Mr. THORNTON. Thank you very much, Mr. Latker, for a very fine summary of your paper. Your paper has been made a part of the record.

Mr. Anderson, I would like to recognize you at this time and ask if you would summarize your conclusions in a similar way so we could go forward with some questions and answers.

[A biographical sketch of Mr. Anderson follows:]

on April 28, 1977 indicated that he would not ask that compulsory licensing of drug patents be continued in the British law.

If the 30-year experience with compulsory licensing in the United Kingdom has demonstrably failed, we would be well-advised in the United States to avoid taking that route. Experience has shown that in country after country, when the patent system is weakened, research and development is diminished. And in the United States where privately financed research and development is the backbone of our technological progress, innovators need to feel confident that there will continue to be the possibility of a reward for risk-taking.

testing and approval process to a marketable prescription medicine, it is not hard to understand why the commercial exclusivity conferred by patent protection is a major consideration.

For products in the fine chemical field such as prescription drugs, herbicides, pesticides, and the like, the specter of compulsory licensing is particularly discouraging to innovators because the research and development cost in time and money is so high, and it costs competitors so little to mimic the commercial product of the inventor.

It should be appreciated that the value of such a high technology product is not the cost of its components or of its production and marketing. The chemical -- once proven to have beneficial utility and developed to assure safety in its intended use/may cost only a few cents a unit to product. But if that chemical can cure a disease, make a farm more productive, or satisfy some environmental need, its true value is determined by what the product does for its purchaser. It is this -- the major component of product value -- that patent rights are designed to protect.

If innovators cannot reasonably expect profits to recover research and development investment(in winners and losers) they will not -- and could not for very long -- continue the research which leads to those products society needs and wants. The early destruction of patent rights --

concept directly threatens our nation's high rate of technological development in socially important fields.

The compulsory licensing dialogue is founded on one of two basic concepts often unexpressed as such. The first is that society's needs in some areas of technology are so great that no industrial organization should have "monopoly" rights in the field. It is implied, though seldom stated, that profit seeking enterprises and free competition in the market place simply can't be trusted to satisfy public needs. In the other concept it is suggested -- sometimes directly stated -- that the social value of some products is so great that private suppliers must be denied what are called "excess" profits. Thus the patent system should be adjusted to provide a mechanism for price control.

We have seen compulsory licensing of patents inserted in the Clean Air Act allegedly to insure that the products of research in that field will be freely available for exploitation by all. It also has been proposed for inclusion in the Energy Research and Development Act, and there are presently about a half dozen bills before Congress proposing it for prescription drugs. There can be no doubt that environmental protection, abundant energy, and good health care are socially desirable goals, and it is understandable that society would like to achieve these goals as soon as possible and at a reasonable cost. It is argued that one way to ensure reasonable cost, rapid results and low

computers, copy machines, instant cameras, life-saving drugs -- has assured profit levels adequate to cover the high development costs from concept to marketing for such inventions. The patent life provides the profit levels for a sufficient time period to assure adequate return after the development costs have been met. Consumers also benefit when these profit levels are looked at enviously by the patentee's competitor who then directs higher levels of profit allocations to research in the more risky but potentially more profitable fields. The number of research dollars so invested depends not only on the degree of exclusivity such inventions enjoy but also on the length of time the inventor is assured exclusivity in the market place for his invention.

In recent years we have seen enacted, or proposed, legislation and regulations that make significant changes in these fundamental elements of our patent system. These changes will have major impact on the private sector's research investment planning. The laws and regulations fall in three major categories. In one category are those relative to the management, i.e., licensing, by the federal government of patent rights obtained under federally funded research: either research performed by the federal government itself or by government contractors. I feel the subcommittee's understanding of this subject, to which Mr. Thornton's HR 6249 is directed, and which has been discussed earlier this morning requires no additional comment on my

is the discovery, development, production, and marketing of products and services to maintain and restore health. Merck is decidedly a high-technology, research-based company: in 1977, we are spending $150 million for research and development. The vast majority of the products we sell were discovered and developed in our own laboratories. It is clear that Merck has a vital interest in an effective patent system and that we have experienced the effects on our business of a wide variety of patent laws and regulations in the many countries in which we do business.

Our private enterprise system has basic elements that I believe are intended to be maintained in any change of law proposed. The first is that freedom of competition is basic to our industrial system and that freedom includes competition in research on equal terms. Second, the reward for effective competition -- the proverbial carrot -- is the profitable sale of a new product of the innovative company's manufacture. In addition, the greater the value of an invention to society, the more likely the new product will return significant profits to the manufacturer.

Our patent system is designed to maximize the benefits to the public from the foregoing principles. When society gives the patentee exclusivity for a limited time in return for the publication of details of an invention it assures the innovator's competitors a jumping-off point for further research in the newly discovered field. For example, when Merck pioneered

Statement By

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before the
Subcommittee on Science, Research and Technology
Committee on Science and Technology
U.S. House of Representatives
Washington, D. C.

May 26, 1977

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Plotkin	Wistar Institute	Rubella Vaccine	1) Wellcome Foundation 2) L'Institut Merieux 3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.)	Approx. millions - Now on market.
Schaffner/Mechlinski	Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb of U. S. A. and Dumex of Denmark	Millions - Clinical trials progressing favorably
Zweig	Syracuse U.	Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium	New Brunswick Scientific Co., Inc., of New Jersy	Millions - On the market since 1973
Lovelock	Yale U.	Gas Analysis Method and Device for the Qualitative and Quantitative Analysis of Classes of Organic Vapors	Varian Associates, Palo Alto, Calif.	On the market
Fried	U. of Chicago	Prostoglandins for possible Treatment of Bronchial Asthma, Duodenal Ulcers, Inflammatory Conditions, etc.	Richardson-Merrell, New York, N.Y.	Several millions - In process of development and testing for marketing here and abroad
Leininger/Grotta et al	Battelle Memorial Institute	Preparation of Non-thrombogenic Surfaces and Materials	C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Louis Mo.; and American Hospital Supply Corp., Irvine, California.	$107,754 - Some products being marketed and others being tested.

SAMPLING OF UNIVERSI.. PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
Walser	Johns Hopkins U.	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfrimmer of Germany and Syntex of U.S.A	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe.
Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions
Kamen et al	Case Western Res.	Methotrexate Assay during Cancer Chemotherapy	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.
Lillehei/Kaster	U. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions.
Blackshear et al	U. of Minnesota	Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.)	Metal Bellows Co.	Undergoing clinical trials $750,000.
DeLuca	U. of Wisconsin	25-Hydroxycholecalciferol for treatment of Osteo-dystrophy with liver dysfunction	Rousel-Uclaf (Hoechst) and	Have applied for equivalen of NDA in France. Approximately $5 million.
			Upjohn	About to apply for an NDA and an NADA. Will spend about $10 million.
DeLuca	U. of Wisconsin	1-Alpha Hydroxycholecalciferol for treatment of Osteo-dystrophy with Kidney Dysfunction	Leo Pharma-ceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. $5,000,000.

IN THIS CONTEXT IT IS APPARENT THAT THE EXISTENCE OF A LICENSABLE PATENT RIGHT IS PROBABLY A PRIMARY FACTOR IN THE SUCCESSFUL TRANSFER OF A UNIVERSITY INNOVATION TO INDUSTRY AND THE MARKETPLACE, AND FAILURE TO PROTECT SUCH RIGHT MAY FATALLY AFFECT A TRANSFER OF A MAJOR HEALTH INNOVATION. I BELIEVE SOME MEMBERS OF THE COMMITTEE ARE AWARE OF THE SPECULATION THAT PRIVATE DEVELOPMENT AND MARKETING OF PENICILLIN WAS FORECLOSED FOR OVER 11 YEARS DUE TO THE LACK OF A PROPRIETARY POSITION NECESSARY TO THE PROTECTION OF THE LARGE RISK INVESTMENT INVOLVED.[7/] IT WAS ONLY AFTER THE UNITED STATES GOVERNMENT UNDERTOOK THIS RISK UNDER THE PRESSURE OF WORLD WAR II THAT PENICILLIN's CURATIVE POWERS WERE MADE AVAILABLE TO THOSE SUFFERING FROM INFECTION.

IN ADDITION TO INITIAL ADMINISTRATION OF THE IPA AND WAIVER PROGRAM DISCUSSED, THE DHEW PATENT BRANCH ACTS AS THE PATENT MANAGEMENT FOCAL POINT FOR ALL INNOVATIONS TO WHICH THE DEPARTMENT RETAINS TITLE. THE DEPARTMENT'S PATENT PORTFOLIO PRESENTLY CONSISTS OF APPROXIMATELY 400 PATENTS AND PATENT APPLICATIONS, WHICH IN THE MAIN ARE DERIVED FROM DHEW EMPLOYEE INVENTIONS. A LESSER NUMBER ARE ATTRIBUTABLE TO INVENTIONS MADE BY EMPLOYEES OF UNIVERSITIES OR COMMERCIAL CONCERNS FUNDED

7/ DAVID MASTERS, MIRACLE DRUG, THE HISTORY OF PENICILLIN, PUBLISHED BY GYRE & SPOTTI, WOODE, LONDON (1946), PP. 104-105 AND
THE LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS, FORMAN, EDITOR, PUBLISHED BY CENTRAL BOOK CO., NEW YORK (1967).

BECOME WELL KNOWN TO INDUSTRIAL DEVELOPERS AND HAVE BEEN GRADUALLY ACCEPTED IN LICENSING ARRANGEMENTS BY A WIDENING CIRCLE OF SUCH DEVELOPERS. THIS COMPARES TO THE VIRTUAL BOYCOTT REPORTED BY GAO OF DEVELOPMENT OF NIH GENERATED DRUG LEADS BY INDUSTRY DURING THE 1962-1968 PERIOD COVERED BY THEIR REPORT. A MUCH MORE DETAILED DISCUSSION OF THE PHILOSOPHY BEHIND THE DEPARTMENT'S PATENT POLICY WAS MADE IN MY TESTIMONY BEFORE YOUR SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS ON SEPTEMBER 29, 1976.

SINCE 1969 THROUGH THE FALL OF 1974 WE ESTIMATE THAT THE INTELLECTUAL PROPERTY RIGHTS TO 329 INNOVATIONS EITHER INITIALLY GENERATED, ENHANCED OR CORROBORATED IN PERFORMANCE OF DHEW-FUNDED RESEARCH WERE IN THE HANDS OF UNIVERSITIES' PATENT MANAGEMENT OR SUCCESSFUL UNIVERSITY PETITIONERS FOR THE PURPOSE OF SOLICITING FURTHER INDUSTRIAL DEVELOPMENT SUPPORT. WE WERE ADVISED THAT DURING THE 1969-1974 PERIOD THESE UNIVERSITIES HAD NEGOTIATED 44 NON-EXCLUSIVE AND 78 EXCLUSIVE LICENSES UNDER PATENT APPLICATIONS FILED ON THE 329 INNOVATIONS. WE UNDERSTAND THAT THE 122 LICENSES NEGOTIATED HAD GENERATED COMMITMENTS IN THE AREA OF 75 MILLION DOLLARS OF PRIVATE RISK CAPITAL. SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES HAS SUBSTANTIALLY INCREASED TO 517.

RELATIONSHIP RESULTS WHEN THE PARTICULAR CAPABILITIES OF THE VARIOUS ELEMENTS, FEDERAL AND NON-FEDERAL, CAN BE UTILIZED TO THE FULLEST EXTENT.[5/] IT SEEMS CLEAR THAT THIS COLLABORATIVE RELATIONSHIP CAN ONLY EXIST IF EACH ELEMENT RECOGNIZES TO THE EXTENT FEASIBLE THE FUNDAMENTAL NEEDS OF THE OTHER ELEMENTS.

IN THIS SPIRIT DHEW HAS CONSCIOUSLY MADE EFFORTS TO CLOSE THE IDENTIFIED GAP BETWEEN THE FUNDAMENTAL INNOVATORS THE DEPARTMENT SUPPORTS AND THE PRIVATE INDUSTRIAL DEVELOPERS WHO MAY BE NECESSARY TO THE DELIVERY OF END ITEMS TO THE MARKET-PLACE. THE STAKE IN CLOSING THIS GAP IS VERY HIGH. IN 1975 APPROXIMATELY 3.2 OF THE 13 BILLION DOLLARS, OR ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES. THE MAIN THRUST OF DEPARTMENT PATENT POLICY AS APPLIED TO UNIVERSITIES HAS BEEN DIRECTED TOWARD:

1. ESTABLISHMENT OF PATENT MANAGEMENT FOCAL POINT IN THE INNOVATING ORGANIZATION TRAINED TO ELICIT INVENTION REPORTS AND ESTABLISH RIGHTS IN INTELLECTUAL PROPERTY ON A TIMELY BASIS FOR POSSIBLE

5/ TESTIMONY BY DR. JAMES A. SHANNON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BEFORE THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMMITTEE ON THE JUDICIARY, AUGUST 17, 1965.

ENTREPRENEUR WILL DEMAND AN EXCHANGE TO GUARANTEE ITS COLLABORATIVE AID. NOTWITHSTANDING, WHERE SUBSTANTIAL RISK INVESTMENT IS INVOLVED, SUCH AS REQUIRED IN DEVELOPING CLINICAL DATA FOR PRE-MARKET CLEARANCE OF POTENTIAL THERAPEUTIC AGENTS AND MEDICAL DEVICES, WHICH IS RARELY UNDERTAKEN IN ITS ENTIRETY AT GOVERNMENT EXPENSE, THERE IS AN IDENTIFIED LIKELIHOOD THAT TRANSFER WILL NOT OCCUR IF THE ENTREPRENEUR IS NOT AFFORDED SOME PROPERTY PROTECTION IN THE INNOVATION OFFERED FOR DEVELOPMENT. THIS POINT WAS MADE WITH SOME FORCE TO DHEW AFTER A 1968 GAO INVESTIGATION AND REPORT ON "PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT-SPONSORED RESEARCH IN MEDICINAL CHEMISTRY."[1/] THIS LIKELIHOOD SEEMS EVEN MORE PREDICTABLE WHEN CONSIDERING THE EXTRAORDINARY ESCALATION IN THE ESTIMATED AVERAGE COST OF SUCCESSFULLY DEVELOPING A NEW DRUG FROM $534,000 IN 1962 TO 11.5 MILLION DOLLARS IN 1973 OR 24.4 MILLION DOLLARS WHEN INCLUDING THE COST OF RESEARCH ON PROJECTS WHICH DID NOT RESULT IN MARKETED DRUGS.[2/] ECONOMIST DAVID SCHWARTZMAN, WHO DEVELOPED THESE STATISTICS, AND OTHERS WHO HAVE REVIEWED THEM FURTHER AGREE THAT RETURN ON SUCH R & D

1/ PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT SPONSORED RESEARCH IN MEDICINAL CHEMISTRY, AUGUST 12, 1968, GAO REPORT B-164031(2).

2/ SCHERER, "THE ECONOMIC EFFECT OF MANDATORY PATENT LICENSING," P. 59, U. S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION, PUBLIC MEETING 1/12/77 AND SCHWARTZMAN, "INNOVATION IN THE PHARMACEUTICAL INDUSTRY," P. 66, 70 and 71.

STATEMENT OF
OF
NORMAN J. LATKER
PATENT COUNSEL
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE before the
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
MAY 26, 1977

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE. MY OFFICE IS ASSIGNED TO THE BUSINESS AND ADMINISTRATIVE LAW DIVISION OF THE OFFICE OF GENERAL COUNSEL, WHICH HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION TO SPEAK TO THE OPERATION OF GOVERNMENT PATENT POLICY, AS I BELIEVE IT TO BE A FUNDAMENTAL CONCERN TO THE LARGER ISSUES OF:

MAINTAINING A FAVORABLE BALANCE OF PAYMENT AND TRADE FOR OUR RESEARCH INTENSIVE INDUSTRIES,

ENHANCING TECHNOLOGY TRANSFER, AND

QUESTIONS OF INDUSTRIAL CONCENTRATION AND CONSUMER PRICES.

IN MOST PART I HOPE TO UTILIZE THESE MOMENTS AS BEST I CAN TO SUGGEST THE IMPORTANCE OF PATENT PROTECTION IN BRINGING

11 days back. And I don't think that was much of a contribution to science.

In reading this supplemental report II it seemed to me that Dr. Lederberg's discussion in appendix 11 said about everything that I would want to say on this matter.

I would like to emphasize something that has troubled me right along which is that the comparative simplicity in terms of the resources and material and plants required for it poses a special problem in my judgment in connection with recombinant DNA research because if we run that research out of the United States, we may encourage running it out of control. If we keep it here in the United States where the forefront of it has taken place, we also keep it where this Congress can indeed keep an eye on it.

The supplemental report also had a passage in it which indicated to me that there is a good possibility that the recombinant DNA molecular research could be a way of bringing scientific translatability between animal cancer experiments, for example, and human. At present we have in our law what I consider to be a prime example of both bad science and bad law in the Delaney clause. It has caused a lot of people a lot of anguish, both the administrators of it and the victims of their necessarily arbitrary enforcement of it. If we had a sound "translator" so that we could in fact progress from the rat or the like to man on some quantitative and generally accepted basis, the arbitrariness would disappear. That is be one of the best things I think that we can look forward to in recombinant DNA research.

I would also object, I think, to the suggestion that appears several places in the supplemental report that DNA research is really the first time that man has had control over genetic development. I am quite well aware, in another context not involving DNA recombinant research at all, of the tremendous effect mutation had on development of the microorganisms by which tetracyclines are produced. It was possible by appropriate mutation in various ways, ultraviolet light and mustard gas and other ways, to cause those organisms to produce or not produce a tetracycline that included chlorine. It multiplied the yields many, many fold and in doing so produced organisms that are very difficult to recognize as being kin to their parents. So this is not new in the sense that we have had genetic manipulation in the production of medicines.

One thing I would like to say as a lawyer about the NIH regulations and guidelines is this: It seems to me that they establish, at least in the lower categories, that all DNA recombinant research is not inherently hazardous. They also establish standards of due care which, if not complied with, would seem to me to justify a civil court in imposing liability in the lower brackets on a showing of negligence and in the higher brackets perhaps on the doctrine of Rylands against Fletcher which is absolute liability when handling an inherently dangerous substance.

In that connection it is interesting, I think, to notice that in a related science-law interface, related in the sense that it is a science-law interface, the approach to weather modification, respected legislative bodies in Maryland and Pennsylvania found that technology inherently hazardous and subject to ban, yet the legislature in Texas ruled that it was not inherently hazardous and negligence had to be proved. They must have been listening to the same scientists but yet they

obviously useful and beneficial advance as improving the quantity and quality of insulin. The part that is of concern to us in the patent end of the proprietary rights aspects of the law in this case, Mr. Thornton, is that patentability and trade secret protection depend upon preventing the publication of the content of research prematurely. This situation is not merely to be considered in terms of the laws of the United States which do provide a 1-year period after publication during which an effective patent application can be filed, for the very sound reason that this country is the only one to have such a broad grace period and the profitability of research very often depends upon securing of foreign patent rights.

Therefore, we have to take into account that premature publication in my judgment means publication prior to the time when an effective patent application can be filed for the Paris Convention countries.

This problem is immensely complicated also, in my judgment, as I testify in my written statement, by the Freedom of Information Act. Unfortunately, the present exemptions in that act are merely permissions for the Government not to disclose and not exemptions which require the maintenance of the information acquired by the Government from private persons in confidence, even if the Government has contracted on that subject.

In that connection, I note that Mr. Singer proposed a registration of projects and some degree of information in that registry obviously to make it effective would include potential information about the content of the research. If that were prematurely disclosed, it would lead to forfeiture of the property. I think such a registry is an excellent approach provided that the legislation creating it makes it clear that that registry is one of information received in confidence and immune from publication and especially from FOIA prying unless—the burden of proof being the other way—unless public safety demands some action and makes disclosure necessary.

These disclosure considerations, I need not remind the subcommittee, I'm sure, have been extensively reviewed by an essentially nonpartisan—at least it appeared to me from reading the roster of names that it was a nonpartisan—President's Biochemical Research Panel in a publication entitled "Disclosure of Research Information" dated June 30, last year, which is a Health, Education, and Welfare publication, No. OS76–515. That in effect I might add is one of the stronger endorsements of the wisdom of the constitutional policy of having a patent system at all.

Now in your letter, Mr. Chairman, you asked whether the basic research is actually within interstate commerce, if restricted, for example, to the grounds of the University of Virginia at Charlottesville and I would say that the answer to that question would be no. That is the answer you would be getting from any Virginian I assume. But I think it is not a logical question in that the hazards we're talking about here are international in scope, Mr. Chairman. And this country not only can but in my judgment should be promoting an international convention for the regulation of the hazards that are foreseen not only perhaps in research projects but even in air pollution and other areas of international concern.

And, if I may remind the subcommittee, the duck shooting regulations by the Federal Government rest for their constitutionality on the treaty we have with Canada because the geese summer in Canada

Section 2(a)(3), describing the right to privacy as a constitutional one, is not literally true, only some aspects of privacy are dealt with in the Federal Constitution.

Section 2(b)(2), setting forth the purpose of Congress to permit individuals to control the use of lawfully compiled records is overbroad; there is no reason why a dossier lawfully compiled for one purpose should not be used for any other purpose for which it could be lawfully used if compiled anew. To say otherwise is to compel useless duplication of effort.

Section 2(b)(4), states a laudable congressional purpose with respect to agency records irrespective of computer usage. See comments on Section 2(a)(2), supra.

The Commission created by Section 5 seems a dangerous thing.

The enactment of HR 7234 (94th Congress, 1st Session), which is the same as the earlier HR 1934, 3235, 3236, 3237, and 3234, would be an unmitigated disaster. It seems incontestable that the First Amendment guarantees every American the right to make and maintain a private data bank and that no anticipatory government control thereof is permissible. Of course, subsequent to its compilation there may, and indeed ought, to be control of uses thereof which cause socially unjustified harm.

An article by Dr. Ruth M. Davis, "Implications of Privacy Legislation on the Use of Computer Technology in Business," appeared in Jurimetrics Journal for Fall 1976.

In a section headed "Security v. Privacy" she makes a clear and useful distinction. She says:

"Computer security insures that—

"Only authorized information enters the system;
"Only authorized users have access to the systems;
"Only authorized programs are run on systems;
"Only authorized changes are made to programs;
"Only authorized individual's access outputs; and
"There is no destruction of the facilities, Information or programs.

" * * * privacy means—

"That there will be no secret data bases;
"That data subjects have a right to access data;
"That data subjects have a right to correct data;
"That data subjects have a right to control dissemination of data; and
"That recordkeepers are responsible for required information controls and notification of data subjects."

As to the six items that "computer security insures" if I understand Dr. Davis correctly, the fifth item says that there is a failure of computer security if a completed printout reaches an unauthorized individual. With deference, such a "leak" of a restricted document is a breach of security not at all different in quality because the document was prepared by a computer instead of by a goose quill pen and the means of preventing such a leak involve the computer not at all. This is, of course, in contradistinction to the second item which says that in a secure computer operation only an authorized person can cause the system to yield an output, whether by visual display or by creating a printout.

As to the five items Dr. Davis lists as making up "privacy," the first item perplexes me. What is meant by "secret?" Surely it was not meant for the item to read "that all data bases will be public." A diary, especially indexed one, is a data base, surely the Constitution guarantees the diarist the right to keep one and to index it by whatsoever efficient means he chooses, setting forth his recollections and impressions of the people and things he has perceived, and to keep it entirely secret. Nor need the diarist be of literary or artistic inclination, he may have the most material of motives, agricultural, commercial, or scientific. Also, governmental agencies must often create secret data bases, the military being the obvious case, but also the evaluation of routes, for example, for public roads where disclosure too soon might lead to disastrous speculation. The fourth item seems to say no more than the laws of libel and slander now say or ought to say. Unless the second item is brought within the frame of my objection to the first item, it seems overbroad. Only a subject who has reason to believe he has been adversely affected by a use made of data, e.g., denied credit or insurance, should have such a right. As to the third item, who is to judge whether the subject's version or the recordkeeper's version of the data is "correct," i.e., more nearly the truth, the whole truth, and nothing but the truth? Does (and shouldn't) a subject open himself to full cross-examination if he asks to "correct" data? For example, credit data show as unpaid a bill for $500 that has, in fact, been paid,

I was disturbed by the reference on page 25 in that it lumped lawyers with ethicists and theologians. Now, lawyers constitute a group of persons linked together by common education, a common experience and into a trade which can be adjudged by abstract professional standards objectively applied.

As such, it may embrace persons in many theologies and many ethics, except for the common ethic of adhering to a professional code. The passage on page 25 lumps lawyers, ethicists and theologians as examples of public interest groups. I find this reference also defective for lack of a definition. I was not helped in this matter by looking at page 108 of Supplemental Report No. II, which listed public interest groups under that precise title. It seems to me that a National Association of Plumbers is also a group of persons whose work is very much in the public interest and one which should certainly be consulted in connection with appropriate regulation of recombinant DNA research in that one of the fruits of that research is, of course, hoped to be improved methods of waste disposal and also, of course, as persons working actively in the day-to-day operation of waste disposal systems, they are persons peculiarily at risk from badly conceived or badly-conducted recombinant DNA research, should the wastes they handle include improper substances released into the systems. I have an inherent distrust of self-appointed public interest groups.

Turning now to another matter suggested by page 17 of Supplemental Report No. II, it would appear that there is a good possibility that the work in recombinant DNA molecular research may lead to methods of identifying animal tumor viruses in such a way that a more certain and meaningful translation can be made between animal tumor-causing substances effective on, say, rodent species and the probabilities of such substances being effective on mankind. Were this to be a fruit of proper DNA recombinant molecular research, it might have the effect of translating, or permitting the translation, of the Delaney clause so notorious in its being a prime example of bad science and bad law into a workable regulation. Turning again to Supplemental Report No. II, I found Appendix 12 and Appendix 13 to be characterized by considerably more heat than light and to contain probably misstatements. Man has had, since earliest times, the capacity to redesign living organisms, as the merest glance at the varieties of dogs, of grapes, of cattle, and of horses, shows. The mule has been with us since pre-history. Yeast strains have been constantly altered in the interests of bakers, brewers and vintners and carefully cultivated and maintained against contamination. We have hybrid corns and other hybrid vegetable products produced without the slightest necessity for recombinant DNA technology. The growth of the tetracycline industry, I am personally aware, was due in a large measure to redesigning the living organisms by which the tetracycline products are made. It will not be of any use to anyone for me to match pejoratives or purple prose with the authors of Appendices 12 and 13, nor need I do so, because the author of Appendix 14 has brought them rather sharply down to earth.

It will be more useful for me to conclude my remarks by commenting on the NIH guidelines from the lawyer's point of view. First, I find it entirely correct that these guidelines are recognized to be subject to frequent revision and change. It would indeed be miraculous if perfect guidelines could be evolved to handle problems which are arising in an area admittedly characterized by vast stretches of unknown fact. However, this much seems to me to be certain. First, that the guidelines seem to set standards of due care by which courts could be guided in judging liabilities and responsibilities in future cases, and also to show that the doctrine of *Rylands* v. *Fletcher* applied only to some recombinant DNA work and not to all. Parenthetically, the doctrine of *Rylands* v. *Fletcher* imposes absolute liability in certain circumstances on persons dealing with inherently dangerous procedures, making them responsible for any damage of which their use of those procedures can be shown to be the proximate cause. It is of interest that other legislative bodies in our states dealing with another science-related subject, the techniques of weather modification, have come up with precisely opposite conclusions in certain instances. Notably, in Pennsylvania and Maryland, the legislatures have found that weather modification should be banned or, at the very least, subject to local government ban, while the legislature in Texas has found that weather modification is not inherently dangerous and that damage resulting therefrom must be shown to have resulted from negligent application of the procedures contrary to the absolute liability doctrine of *Rylands* v. *Fletcher*. The NIH guidelines take the Texas view as to some DNA recombinant work; the Pennsylvania view as to other.

To end on a personal note, it would seem to me that the guidelines are, if anything, unduly restrictive in that I note on page 31 that among the types of experiments prohibited are "deliberate formation of recombinant DNA's containing

there is no grace period and the patent rights go to the first to file an effective application. In consequence, any fair regulation of DNA recombinant molecular research, especially as it progresses from the basic to the application stage, will require that effective secrecy be maintained until an opportunity to file an effective patent application has been afforded the proprietors of the invention.

Leaving patent protection to one side, there are two other areas where premature disclosure can have an undesirable effect on research programs. The first, and most obvious, is, of course, the effect of disclosure on the ability of the owner of the research information to protect his trade secret position. Another area of great importance is in the peer review process much used by Government agencies giving grants in support of research programs to determine which proposed programs are worthy of support. It is unfortunately true that the entire scientific community is no more free of greed and underhandedness than the entire community of the Bar or, indeed, the entire community of politicians. In all three of these areas in which at least a temporary period of secrecy is apparently essential, there is a well-recognized exception in that disclosure to a small number of persons who accept a clear obligation to keep the subject matter disclosed to them confidential until subsequently released by its proprietor does not have the effect of a public disclosure. All three of these areas are ones in which the Freedom of Information Act has proved troublesome in its application. It has been said that information, even though coming from private sources, for example, information obtained by the Department of Justice in one of its sweeping preliminary antitrust investigations, or information obtained by a research funding agency preliminary to grant, is subject to forced disclosure under the Freedom of Information Act by persons who would be entitled to such disclosure if the information were of Government origin. I see no way out of this dilemma except a blanket exemption of information coming into Government hands, that is to say, becoming known to officials of the Government, only through the exercise of governmental coercive power or the purse power of the grant process, where the information is considered secret by its proprietor unless specific court authority for its release is obtained with due process and the Government undertakes to reimburse the owner for his private property thus put to a public purpose.

These disclosure considerations, as I am sure this subcommittee knows full well, have been extensively reviewed and affirmed in a Report of the President's Biomedical Research Panel entitled "Disclosure of Research Information," dated June 30, 1976 (Department of Health, Education and Welfare Publication No. OS 76–513).

Mr. Thornton's letter asks the question whether basic research is actually within interstate commerce, even in those instances in which no products are transported across state boundaries. With deference, it seems to me that while the answer to this qeustion is, "No," the global implications of the accidents feared to be possible from ill-conducted DNA recombinant molecular research make this question largely academic. In short, in my view, the doctrine of *Missouri v. Holland* which, you will recall, made certain federal regulation of migratory birds constitutional because it was the subject of a treaty concerning migratory birds that summered in Canada and wintered in the United States, would supply the constitutional way to national DNA research regulation. It would seem clear to me, therefore, that the United States could, and probably should, urge the creation of an International Convention governing not only the conduct of hazardous research, that is to say, research with hazards of international implication, but including, perhaps, international pollution problems and, in such an International Convention find the constitutional basis for appropriate legislation. It seems to me that the question we really confront is how to bring sound and well-considered science to the aid of the terms of such legislation.

I claim no special expertise in, or even any very great familiarity with, the parameters of recombinant DNA molecular research. I shall base my comments, therefore, essentially upon my reactions to the Supplemental Report No. II previously cited.

In order to determine whether sound science is being applied to create sound law, it has always seemed to me necessary for people examining the problems to define the terms. I have essentially done so in another context but I believe the definitions to be entirely appropriate here and I venture them now. "Science" means "Any field of human knowledge that may be illuminated by a valid experiment." "Law" means "The rules of conduct enforced by government, and includes the judicial and legislative processes by which those rules are formulated and the judicial and administrative processes by which they are enforced." One of the strongest bases for my definition of "science" is to be found in the work of the same John Platt who was cited by the author of Supplemental Report No. II

STATEMENT OF W. BROWN MORTON, ATTORNEY AT LAW

Mr. MORTON. Thank you, Mr. Chairman.

I am W. Brown Morton, Jr., a lawyer in private practice with the firm of Morton, Sutherland and Roberts at 1800 M Street NW., here in Washington. I received a bachelor of science degree in 1936 and a bachelor of law degree in 1938 from the University of Virginia.

Parenthetically, I would interject that the science I learned in 1936 not only did not include recombinant DNA but it did not take into account the energy to be created out of matter, so as a scientist I am woefully out of date, but as to law I am more current.

I have been active in the practice of patent and related law for nearly 40 years (5 years in the Army in World War II excepted), here and at New York. I am a member of the Virginia, New York and District of Columbia Bars. I have taught a one-term course in Intellectual Property Law at the Law School of the University of Virginia at Charlottesville regularly since 1959. I have been active in bar association work, including lecturing at continuing legal education programs for many years.

I was president of the American Patent Law Association in 1964 and have since then continuously represented that association as its delegate in the House of Delegates of the American Bar Association. I am presently cochairman of the American Bar Association of the National Conference of Lawyers and Scientists. Cochairman with me for the American Association for the Advancement of Science is its President, the Honorable Emilio Q. Daddario. I am sure Mim Daddario is well known to the members of the subcommittee. It is the mission of that conference to seek ways to improve the interaction of law and science, especially by improving communication and understanding between professionals in both fields.

I must stress that the testimony I shall give here and the views I express are entirely my own and in no sense represent the views of, and are in no way authorized by, any institution or organization with which I am affiliated.

The ABA house of delegates has the admirable policy of requiring in any report submitted to it by any ABA member a disclosure of any material interest in its subject matter by reason of specific employment or representation of clients. In the spirit of this policy, I state to the subcommittee that neither I nor any firm of which I was or am a member has to my knowledge ever had any employment involving recombinant DNA nor do I or my present firm have as a client any of the seven companies stated on page 51 of the subcommittee's Supplemental Report II of December 1976 to be currently engaged in recombinant work.

Mr. THORNTON. Mr. Morton, I am reluctant to interrupt but I think this might be an appropriate time to do so. We are at present conducting a vote on the floor of the House and I think it is important that I attend that vote. It will take me about 7 minutes to make the round trip. So it seems to me this might be an appropriate point to break for a seven-minute recess.

Mr. MORTON. That would be most agreeable.

Mr. THORNTON. We are in recess.

[Recess.]

Mr. THORNTON. The hearing will come to order.

more information about risk of injury and efficacy of containment will become available. And amendment to the guidelines reflecting the new data should be encouraged and should not be made difficult to accomplish.

Second, I have excluded from my presentation any discussion of the wisdom of introducing into commerce for agricultural or human therapeutic uses new products arising out of recombinant DNA research. I believe that discussion to be irrelevant to the present task. I urge the Congress to treat quite separately the significant and difficult issues that are likely to surface if we gain the capability to realize upon the now-still-fictional scenarios of genetic engineering and agricultural revolutions.

The real aim now is to assure reasonable safety. There appears to be broad public agreement that the NIH guidelines afford such assurance. Their application to all recombinant DNA research should be readily achieved without imposition of regulations which will generate myriad adverse consequences not related to safety.

Thank you, Mr. Chairman.

Mr. THORNTON. Thank you very much, Mr. Singer. I noted with interest your listing of the possible regulatory mechanisms which might inhibit research. I assume that there may be others which are not listed which also might be used?

Mr. SINGER. I think the imagination of man and woman is sufficient unto that task, frighteningly so, in my judgment.

Mr. THORNTON. Mr. W. Brown Morton, our next witness, is an attorney here in Washington, D.C. We welcome you to the committee and ask that you proceed.

[Biographical sketch of Mr. Morton follows:]

STATEMENT OF DANIEL M. SINGER, ATTORNEY AT LAW, WASHINGTON, D.C.

Mr. SINGER. Mr. Chairman, thank you very much.

My name is Daniel M. Singer. I am an attorney and a partner in the firm of Fried, Frank, Harris, Shriver & Kampelman, 600 New Hampshire Avenue NW., Washington, D.C.

I have been a not disinterested observer of the recombinant DNA debate since its earliest rumblings in 1973. And I was one of the four lawyers at the Asilomar Conference in February 1975. I have been a fellow of the Institute of Society, Ethics & Life Sciences since 1970. I represent here no one but myself, notwithstanding I am married to a scientist, Maxine F. Singer, who has, among other things, testified before you recently on the subject of recombinant DNA research.

Mr. THORNTON. If I may interrupt to say that the testimony was most illuminating and she was a very fine witness.

Mr. SINGER. Thank you.

I appear today at your invitation. Let me say at the outset that I have a very high level of confidence in the ability of the community of basic research scientists to deliver on the one item that that community has promised from recombinant DNA research, namely, a vast and reasonably rapid increase in our knowledge and detailed understanding of living organisms.

And I would characterize that increase as a "benefit." I have a similarly high level of confidence that the community of industrial scientists will exploit that increase. I am not as yet prepared to characterize the results of such exploitation as, on balance, a net "benefit."

Some of the results may be "benefits" and some may not. I am convinced that our relatively open political processes, including the marketplace—Laetril notwithstanding—are likely to make reasonably sound, albeit very difficult, discriminations between those technological exploitations which ought to be, and those which ought not to be, offered to or imposed upon us.

I am also convinced that we ought not even attempt to make discriminations between good and bad knowledge flowing from basic research. In an open society—that is, one which, among other things, is susceptible to change—it is in my judgment morally and politically wrong—and very likely unconstitutional—for a political body to say: "We ought not to know," so long as we are reasonably assured that no injury will be inflicted in the acquisition process. I am persuaded that with the wide acceptance and observance of the NIH guidelines among those receiving Federal support—and the imminent extension of those or similar guidelines to non-Federal activities—we will have such reasonable assurances of safety.

However, in mandating nationwide applicability of guidelines for research safety, Congress is also in a position to encourage or stultify the research process, quite independently of the level of funding for research.

To the extent that Congress elaborates the regulatory bureaucracy, a price—in my judgment a very high price—will be paid in discouraging the research effort. In contrast, to the extent that the regulatory mechanisms remain trim and at the minimum level necessary to assure compliance with safety standards, research will continue to flourish.

3. June, 1962 (date or organization) to July, 1964:
   Director and Secretary-Treasurer
   Council for a Livable World
   An organization which channels campaign contributions to liberal Senators and Congressmen.

4. January, 1970 to date:
   Fellow
   Institute of Society, Ethics and The Life Sciences.

5. January, 1972 to 1977
   Vice President
   Institute of Society, Ethics and The Life Sciences.

6. September, 1971 - May, 1972:
   Visiting Lecturer
   Graduate School
   Weizmann Institute of Science
   Rehovot, Israel.

Pre-legal Education

Swarthmore College, B.A. with honors, 1951
Open Scholar (full tuition scholarship for four years awarded to five entering male students
Editor-in-Chief, weekly campus newspaper
Chairman, Men's Executive Committee
Student Council
Varsity Tennis and Soccer
International Relations Club
Dormitory Proctor
Intercollegiate Conference on Government
Book and Key (Senior Men's Honor Society)
Permanent President, Class of 1951

5. Legal research performed at Yale Law School for the following professors in connection with the listed publications:

Fowler V. Harper & Fleming James, Jr.
"The Law of Torts" (1956)
Fleming James, Jr.
"Tort Liability of Occupiers of Land: Duties Owed to Licensees and Invitees," 63 Yale L.J. 605 (1954)
John P. Frank
"Fred Vinson and the Chief Justiceship," 21 U. of Chi.L.Rev. 212 (1954)
Richard C. Donnelly
"Unconvicting the Innocent," 6 Vand.L.Rev. 20 (1952)
Harry Shulman & Fleming James, Jr.
"Cases on Torts" (2d ed. 1952)
Addison Mueller
"Contracts in Context" (1952)

Publications

1. Note, "Discretionary Administrative Jurisdiction of the NLRB under the Taft-Hartley Act," 62 Yale L.J. 116 (1952)

2. Comment, "International Copyright Protection and the United States: The Impact of the UNESCO Universal Copyright Convention on Existing Law," 62 Yale L.J. 1065 (1953)

This essay was awarded second prize in the Nathan Burkan Memorial Competition at Yale Law School in 1954, and was selected as one of the six best essays on copyright law in the national Nathan Burkan Memorial Competition for 1954. The essay has been published in "Copyright Law Symposium, Number Seven" (Columbia University Press, 1956).

CURRICULUM VITAE

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August 1, 1975

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Date and Place of Birth

October 10, 1930
Brooklyn, New York

Marital Status

Married June 15, 1952 - Maxine Frank
Four children (ages 16, 14, 13 and 11)

Legal Education

Yale Law School, LL.B., 1954
Top 25% of class
Editorial Board, Yale Law Journal
Director, Thomas Swan Barristers' Union
Legal Aid and Public Defender
Yearbook Board

they were doing it, in actual practice they have tended to receive substantive due process in the area of individual rights. The right of privacy, for instance, has been viewed by some of the justices not as a separate constitutional right but simply as an aspect of liberty under the due process clause.

So that doctrine still exists. It would have some application but normally most of the basic questions would be decided in terms of the first amendment under normal circumstances. Of course, procedural due process is an entirely different matter.

Mr. THORNTON. Let me return for just a moment to the question of whether a national standard should be established and preempted by the Federal Government. If that were to be the direction of legislation, might it be appropriate to provide for some appeals mechanism or review mechanism so that a local institution of government might suggest a waiver or application of somewhat different standards because of particular circumstances which that institution felt were applicable to its circumstances and which should be reviewed?

Any thought with regard to that?

Mr. EMERSON. You mean to give a local government a standing to test the constitutional issues or the legal issues in a court proceeding?

Mr. THORNTON. Not only to test but for example to make an assertion that the circumstances at that particular place were such as to require maybe a higher standard to be applied or to have a further restriction than that in the national standard.

Mr. EMERSON. You mean an opportunity to impose additional restrictions.

Mr. THORNTON. But to have it——

Mr. EMERSON. Decided by a court, you mean?

Mr. THORNTON. To be decided by the institution charged with enforcing the standards.

Mr. EMERSON. I would certainly—at least as I think about it for the first time—agree with giving the local subdivisions and so forth what is called standing in court to raise any legal question that comes up. Whether or not the agency administering the whole series of regulations should have authority to modify them with respect to local situations, I think I would agree with that. But I have not thought about it very much.

Mr. THORNTON. Perhaps this question is one which might be addressed for later response, if you would like to submit some additional comments. Mr. Green, do you have any comments?

Mr. GREEN. Well, I would generally be in favor of the greatest possible flexibility and the least possible rigidity in regulations. So I would generally sympathize with that. I do think, however, that there are some other problems we ought to be aware of.

We talk about preemption in a rather blithe fashion and I think there is at least some constitutional doubt.

We see this now argued in the nuclear power area. There is some constitutional doubt as to whether Federal preemption of regulation would oust a State or local body from prohibiting an activity all together under its zoning power, for example.

I think that is an essentially unresolved question which I think we are going to have to be aware of.

DNA to the best of my understanding, at this point anyway, is fundamental basic research.

I do not know if we have ever undertaken to regulate that. For example, when we were regulating nuclear development, nobody was putting a lid on high energy particle physics. FDA regulations did not stop people like Jonas Salk. My question is would you think that this committee, or other committees which are considering regulations, would have a reasonable basis to draw legislation in such a manner as to take cognizance of this fact, and therefore make it perhaps less stringent, however it may come out, than we might with things that are already known or have a much more probable possibility of harm?

With DNA we don't know.

Mr. GREEN. In the atomic energy area basic research in broad areas involving source material, byproduct material is subject to licensing. The power to license implies the power to prohibit.

Mr. YEAGER. This is the DOD stuff, and the same situation as with chemical or biological warfare. Do you think there may be a basis for a distinction?

Mr. EMERSON. I do not think that in legal or constitutional terms there is an exact equivalency between the scientific concept of basic research and applied research. I think that the first amendment protections would almost automatically apply what is generally called basic research. But they would also apply it seems to me to a good deal of applied research. I think that that concept is not exactly the one that we are trying to strive for.

I might also say that I think the proposed controls over recombinant DNA research do go further than anything that has really been done so far because the existing controls over human experimentation or animal experimentation and so forth are dealing with a biological level. Now we are down to a fundamental molecular or cell level of control not involving humans or animals. That really goes further and has more serious implications than anything that has been done so far.

I agree that drawing the line between expression and action is very difficult and runs into very deep psychological theories about body and mind and so on. It is simply that it is the best we can do in terms of trying to draw lines.

I think a major difference between my colleagues here and myself is that I feel that lines can be drawn in terms of basic legal principles which correspond to the function of the first amendment. I think they are much more skeptical about applying legal rules here at all, and therefore, in effect they are defeatists in my view because they think you cannot apply constitutional principles to this situation, that it is not a constitutional problem. I disagree with them. I think that we have solved a great many of our problems in constitutional terms and that an effort should be made to apply constitutional principles in this situation.

Mr. BARRON. I think now there are some things that we agree on and there are some things that we do disagree on. That is a matter of disagreement, I think, whether it is defeatist or not being another matter. As I said in my paper, I really have great difficulty with the speech-action distinction if it were used in this area.

precedents for other areas of scientific research, thought, and expression in the future.

So it seems to me that we should approach this with a great deal of care and thought as to not only the DNA recombinant research issue but also with regard to all scientific inquiry, thought and action. Would you agree with that? Are you in a position to make an observation with regard to the applicability of this standard?

That is, across the board?

Mr. EMERSON. Yes; I would agree with that. It seems to me that that is basic to the solution of the first amendment problem which as I say I feel is a very serious one here. I would also say that the Supreme Court's approach to first amendment questions, in which they do not extend absolute protection to whatever conduct it is that comes under the first amendment, makes the problem from their point of view less serious because they do not have to define it so carefully.

As in the *O'Brien* draftcard burning case, they can say well, it is mostly action, but there is an element of expression here so we will apply first amendment protections, but then apply them by a mere reasonableness test. So they don't concentrate so much on the distinction between expression and action. But I agree with you that it is very important that the development should be in that direction because it seems to me that the basic idea and the basic policy of the first amendment is that ideas, thoughts, beliefs, opinions, expressions, theoretical inquiries, all should be allowed to proceed no matter how bold they are, and that the line has to be drawn at the point where the social interest is in the action, to a certain extent actual physical conduct on the part of the persons involved.

I think that is the basic theory of the first amendment. It will be very important, therefore, to follow through on that.

Mr. THORNTON. With that statement let me go one step beyond. It has been suggested to us that there may well be a distinction between the theoretical academic pursuit of knowledge and the laboratory experiments associated with DNA research, some of which may be required to be conducted in very tightly controlled circumstances; that there may be a distinction between that and the commercial utilization of the results of recombinant DNA work, making available on the marketplace, for example, insulin, if the experiments that were reported in yesterday's paper do work out and eventually we get to the point where insulin would be produced by bacteria.

There might be a different regulation with regard to setting up facilities for production of insulin and the marketing of insulin or the use of other agents which are developed—from those standards which are used in doing the research at the beginning.

Mr. EMERSON. I would agree with that. I would think that the first amendment would probably have very little application to the commercial application of the results of the experimentation, of the research and experimentation. That would be largely controlled, perhaps almost exclusively controlled, by other constitutional principles.

At the other end, the theoretical development it seems to me is clearly protected. The problem seems to me to arise in the area of experimentation. Now experimentation is such an integral part of scientific research that it is like running a printing press to publish a newspaper. Freedom of the press means more than writing articles in

there was a colloquy between him and the bench. Brandeis was asked whether he wanted to give the impression that the evidence he presented in his brief was the truth with respect to these matters.

He said no; that was not his purpose. What he wanted to do was merely to say that it could be reasonably held by the legislature that reasonable men in the legislature had reason to believe on the basis of this evidence that these things were true.

He made a clear distinction in the discussion that took place between claiming to present the truth of the matter and claiming to present opinion in the community with respect to these matters. The difficulty of that thing has something to do with what I was saying about amicus briefs. The difficulty of the Brandeis brief is there is no opportunity to impeach that testimony.

It is much better to have this on the record somehow and allow the other side—that is one trouble with an amicus brief. It is presented as the opinion of the ACLU or the antidefamation league or whatever. The issues are such that they should be resolved before, to the extent that they can be.

I would like to make a comment that touches on two things. One, the question of Federal versus local regulation and the competence of the courts and the legislatures to deal with this problem. Over the years one of the things that has struck me has been the willingness of Congress and other legislative bodies to treat the area of science as something that is in a sense sacrosanct, that you require a special education to understand public policy issues involving science, that only scientists or engineers are capable of participating in those decisions.

I think unnecessarily, if I might even be a bit critical of the legislative process, you have permitted scientists to come before you and make their pitches for money and other things in their own exotic language.

It seems to me there is another way that this could have been done. One could insist that when scientists inject themselves into political and legislative processes, that they ought to be required to speak to the policymakers in the language of ordinary political discourse.

As one who has been playing around with this for a long time, these issues, I have no education in physics, chemistry or biology, recombinant DNA molecules but somehow I managed to ask the right questions to get the information in my hands in a form that I can use.

I don't think there is anything that is so esoteric about some of these scientific issues that they can't be handled the same way tax policy and labor policy and farm policy are handled.

The second comment which is related to that is I personally would be in favor of Federal preemption of regulation in this area for one very pragmatic reason and that is that these little beasties that might get out into the environment as a consequence of an experiment performed at Cambridge, Mass., could conceivably make people sick in New Mexico, Arizona, and California.

These organisms do not respect geographical boundaries as a matter of fact. The reasons are persuasive why there ought to be global regulations and not merely national regulations.

Mr. BERNS. Mr. Chairman, I suspect that the committee is going to have to go beyond the question of regulation by funding or withholding funds.

Mr. THORNTON. Oh, yes.

Mr. BERNS. I gather, for example, the drug companies themselves are financially capable of conducting this research and have strong reason to do so. The committee is probably going to have to face the further constitutional question of propriety.

Mr. THORNTON. I think this is a very good observation. I wanted to get past the threshold question of what limitations there might be if any on conditions placed upon the use of public funds. Then we should I think turn to the next question of nonpublic funds. Mr. Barron, do you have any comment?

Mr. BARRON. No; I don't. I have some comments on matters of agreement and disagreement with respect to the constitutional law problems generally but you may want to do that another time.

Mr. THORNTON. I think this might be a good time to do that. Go ahead.

Mr. BARRON. First let me say that as a former student of Professor Emerson I am never very happy when I have not persuaded him about something which is the case here this morning. Let me try, because I think it is true to a considerable extent, to revive something that my colleague Harold Green said, which is that he agreed with all of us.

I really do think that there is considerably more agreement here than the various doctrinal choices by the panelists might indicate. The first thing is that I did not intend to equate this problem with obscenity. If I left this impression, I am really very sorry because it was not my intention. Certainly the obscenity cases and regulations are far more trivial than this problem. And I did not intend to suggest that that body of regulation, unhappy in terms of all its inconsistencies and so forth, as it is, should be a model for anything, much less this particular controversy.

The only reason I mentioned this was to suggest that even in that area, there has been considerable attention and respect given to the right to communicate and therefore also by implication the right to investigate. I would make the observation that it is difficult to analyze a problem like this without making reference to the existing first amendment law such as the obscenity law and I notice that Professor Emerson himself suggested as two approaches from this committee two doctrines that come from the obscenity law, and with respect to the Cambridge City Council and I said I thought academics should be more patient with the Cambridge City Council, I would like to say a couple of things about that.

I think on balance with respect to the views of Professor Emerson, I would support what he is saying; if you are going to do anything in this area, you ought to have a national standard. On the other hand I am troubled by saying, "Well, the majority will always be unhappy and that is why we have the first amendment to protect the minority view."

You are talking about things that go far beyond the exchange of opinion. This goes to a final point that I want to make. Perhaps, it is related to my feeling that the speech-action approach is inadequate to deal with this problem. I refer to my discussion about the role

our legislatures. While an argument about a right to scientific freedom may be a useful piece of rhetoric in political debate, we should not take the existence of such right too seriously. In short, the principal point that I would leave with you today is that the boundaries of scientific freedom, at least in terms of current issues, are established primarily through the political process and are not rooted in constitutional law.

It requires only a moment's reflection to appreciate that there is really nothing new or novel from the standpoint of the NIH guidelines on recombinant DNA molecule experiments, or the Cambridge restrictions on such experiments. We all realize, or should realize, that government in the past has imposed restrictions on where and when certain kinds of research may be conducted. Obviously, city zoning laws may preclude experiments with explosives in the center of an urban population center, and it would probably be regarded as a legal nuisance if the explosives were experimentally detonated within earshot of the community at 2:00 a.m. We know that scientists are not free to experiment with human subjects or the fetus as they see fit. We know that there have been restrictions on the use of animals or cadavers in scientific research. We know that the Food and Drug Act and the Atomic Energy Act restrict and regulate certain kinds of research. We know that limits on the use of classified information may impede or bar certain scientific research programs. Indeed, within recent weeks, Dr. Barry Casper, writing in the Bulletin of the Atomic Scientists, has raised the question of a moratorium on development of laser enrichment of uranium.

not second-guess the legislature or executive as to the wisdom, desirability, or necessity for regulation. Thus, there has never been any doubt in my mind that a city's prohibition against recombinant DNA molecule experiments within city limits does not violate any constitutionally protected right of scientific inquiry where the city may rationally -- even though perhaps not reasonably -- have believed that such experiments might endanger the health and safety of the public.

At this point it is necessary to draw another kind of distinction -- between government regulation of a scientific activity and a government decision not to fund that activity. We sometimes forget that government has no moral or constitutional duty to support scientific research, no matter how beneficial the hoped for results,* and that no scientist has a constitutional right to have his research projects funded by the government. I am reminded of Freeman Dyson's article in Science in 1965 in which he argued that NASA's decision not to continue funding Project Orion represented "the first time in modern history that a

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* See, for example, my exchange with Bernard Davis, Volume 265, Annals of the New York Academy of Sciences, Ethical and Scientific Issues Posed by Human Uses of Molecular Genetics, p. 176 (1976).

abstractions and turns to experimentation, he moves within the range of action that may enjoy only some, or perhaps very little or no, constitutional protection. To the extent experimentation could be constitutionally protected, freedom would vary inversely with the degree of perceived impact on persons and the environment. Thus, where scientific research involves experimentation with human or animal subjects or where it impinges upon the community, it would clearly become subject to regulation. It is interesting to note at this point that Hans Jonas, writing in the August 1976 Hastings Center Report, reaches the same conclusion from the moral perspective. He tells us, eloquently, "The granting of freedom to thought and speech . . . does not cover action, even if subsidiary to thought. Action is always subject to legal and moral restraints."

I think, so far as I have gone, scientists would sense intuitively that what I have said is correct. They are, after all, surely aware of a multitude of legal restraints on what they can do and where, when, and how they can do it. Where many would probably part company with me is on the question of where the burden of proof lies before government may properly restrict scientific freedom.

In my comments this afternoon, I intend first to discuss these issues from my dual perspective as a teacher of constituional law and as a student of public policy for science and technology. In doing so, I shall not consider whether there are or should be any limits on scientific freedom as a matter of morality or policy, but only whether limitations are permissible as a matter of constitutional law. I shall then say a few words on the program on which the Subcommittee on the Boundaries of Scientific Freedom has embarked.

To begin with, I am not aware of any precedent or legal authority that clearly supports the proposition that there is a constitutionally protected right to pursue knowledge or to engage in scientific inquiry. I believe, and I am prepared to argue, however, that such rights are implicit in the First Amendment freedoms of speech and press; and for purposes of this paper it is assumed that the Constitution guarantees and protects such rights to precisely the same extent as speech and press. Parenthetically, it seems clear to me that a right to scientific inquiry can have no greater constitutional dignity than freedom of speech. Let us therefore explore the boundaries of freedom of speech in the effort to understand the boundaries of scientific freedom.

THE BOUNDARIES OF SCIENTIFIC FREEDOM*

Professor Harold P. Green
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* Presented, February 21, 1977 at the Annual Meeting of the American Association for the Advancement of Science, Denver, Colorado.

amendment considerations. I suspect one of the reasons why this arises in this particular context of recombinant DNA molecules is because the biomedical community has in fact been free from regulation for so long a period of time and in addition beacuse the biomedical community regards itself as intrinsically performing intrinsically good works for the improvement of humanity.

In any event my own view is that the arguments about freedom of scientific inquiry—and I am devoted to the freedom of scientific inquiry, even though these arguments are dressed in first amendment garb—are really in the realm of political rhetoric and cut very little ice as a practical matter from the standpoint of constitutional law.

One of the issues as I mentioned before is where does the burden of proof lie? Must the Government prove that these experiments are harmful before it regulates? Or is it enough that there is simply a rational basis for that? The bottom line of that point is, as I mentioned will the biomedical regulate itself or will it be subject to Government regulations?

Indeed at the conference, there was almost a paranoic dread on the part of the scientists there about the spectre of regulation. One group of people said you know if we talk too much about this in the presence of all these people from the press, we are going to get Government regulation. Another group of scientists said if we don't talk about it, we are going to get Government regulation.

They were all opposed to regulation. Scientific, codification is even worse than regulation. Detailed code is the worst of all possible worlds. Also implicated in this is the question about the fuzziness between harmful effects of experimentation and applications and the possible harmful use of knowledge that will result from this.

It struck me as a striking paradox that the scientific community has no hesitation whatsoever about urging the Government to spend money on scientific research because of the beneficial results that may flow from that knowledge while they refuse to acknowledge that the Government has any right not to spend money because of possible harmful results that may result from the use of knowledge.

It is indeed a one-way street. As I pointed out in my prepared statement, in 1965, Dr. Freeman Dayson, eminent member of the scientific community in an article in the Bulletin of the Atomic Scientists entitled the "Murder of Project Orion" made the remarkable argument that a decision by NASA not to support Project Orion which was a system of spacecraft propulsion by tossing small atomic bombs or hydrogen bombs out of the rear of a spacecraft in order to give it a push, that the decision by NASA not to fund that research was the first time in American history that a decision was made to suppress a technology for purely political purposes. That is a remarkable kind of statement.

But that kind of thinking is in many respects characteristic of the scientific community as they deal with this problem. Finally, I will simply say that in my view I have no doubt whatsoever that the Government has the constitutional power and indeed I would argue a fundamental political duty to use its funding power to support or not support particular kinds of scientific research so as to encourage that

Mr. EMERSON. I think the court has not followed that case. I think that was a decision in which they were dealing with something that they considered action, the burning of a draft card, which they considered totally outside the area of first amendment protection. Therefore they just gave it the minimum amount of protection they felt was appropriate.

That test does involve a less drastic means component. The case indicates that, yes, they should continue to apply that. But the rest of that decision does not impose a compelling reasons test with the burden on the Government to establish the compelling reasons.

The main part of the O'Brien test is simply a reasonableness test, and that I would disagree with. I really do not think the Supreme Court has followed that test. I think the latest decision, and the exposition of these ideas in situations as near to this as there are, and there are no exact duplicates in Supreme Court decisions, is the *Buckley* v. *Valeo* decision in which they examine very carefully the reasons that Congress offered for regulations of freedom of expression in political campaigns and applied the compelling reasons and less drastic means test.

That is the approach which they will take. I think the *O'Brien* case is not one which they have followed, at least consistently, and I think one they should not follow here.

Mr. THORNTON. Thank you, Mr. Emerson.

Mr. Green, I am delighted to have an opportunity of visiting with you again. We have had the pleasure of sharing a number of occasions in which we have both addressed problems. It is a pleasure for me today to hear your presentation. You are welcome. Please proceed.

[A biographical sketch of Mr. Green follows:]

HAROLD P. GREEN

Harold P. Green (University of Chicago, A.B. 1942, J.D. 1948) is Professor of Law and Director of the Law Science and Technology Program at the George Washington University National Law Center. He is a Founding Fellow and a member of the Board of Directors of the Institute of Society, Ethics, and the Life Sciences (The Hastings Center), and has written extensively on legal and public policy issues relating to science and technology. Professor Green is a member of the American Association for the Advancement of Science's Committee on Scientific Freedom and Responsibility and is the Chairman of that committee's Subcommittee on the Boundaries of Scientific Freedom.

STATEMENT OF HAROLD P. GREEN

Mr. GREEN. Thank you very much, Mr. Chairman. I don't think there is much I can contribute to an exposition of constitutional law. Suffice it to say I am in agreement with all three of my colleagues, even with Professor Emerson who attempted to divorce himself. [Laughter.]

Mr. GREEN. I think one of the problems is to the extent that I have any disagreement at all, reflects the inherent fuzziness of the issues on which we are all speaking. I would like to try rather than repeat what has been said, to attempt to proceed—to provide some perspective which may be relevant to the problem.

The perspective that I would like to offer is derived from a number of sources, derived from my longstanding interest in public policy decisionmaking processes for science and technology, from my long involvement in the problem of recombinant DNA molecule mat-

ance to inquire further into the forms of life or into the transformation of man is simply not a compelling constitutional reason.

I think that is essentially the holding of *Griswold* v. *Connecticut*, the birth control case, of *Roe* v. *Wade*, the abortion case, and of others. Moral or ethical principles of that sort held by a minority, or a majority even, are not adequate grounds for preventing others entering into a search for the truth as they see it.

On the other hand, compelling reasons would be serious dangers to the health and safety of the surrounding population. I come out at the same place as before using the orthodox Supreme Court test.

The second half of the test is also of immense significance because I think that it is the second half of the test that will be of more detailed application. Once one has resolved the very basic initial questions, you go on to this area.

The regulations have to utilize the least drastic means. Now that involves a number of things. One is that there should be a bare minimum of restriction. Where regulation is adequate, the legislation should not prohibit. Regulate rather than prohibit. Where the restriction can be temporary rather than permanent, it should be temporary. Where it does not need a license system or a system of prior restraint, that should be avoided. The least onerous burden should be at every point placed upon the experimentation that is being regulated.

Second, I think that it is possible to argue, even as a constitutional matter, that the regulations ought to emanate from a single source; namely, the Federal Government. Regulations imposed by States and local communities create such danger of suppression of scientific inquiry that even as a constitutional matter much less a policy matter, one should argue that the least drastic means test requires that the regulations be limited to a Federal source.

The problem is after all, if it exists at all, a national one as has been described. The University of California at Berkeley cannot move out of Berkeley to another area. The impact of allowing local regulations would in my judgment be disastrous.

Finally, I want to mention another aspect of first amendment doctrine which has come to be quite important in recent years. In those cases where the Supreme Court has under its orthodox theory allowed some regulation, as in obscenity cases and others, it has at the same time as a price for allowing that regulation of expression required that the regulation proceed according to very strict procedural safeguards. Thus in the case of movie censorship boards, it is required that the Government agency itself bring a proceeding in court within a very limited amount of time to have a court decision of the question of whether the film involved was obscene or not.

The Supreme Court has imposed other strict regulations of that sort. I think that what is sometimes called first amendment due process would be particularly applicable here in many situations.

Again I will not go into detail but mention two things. One is court review. I disagree with Professor Barron's first statement on this. He corrected it in his last page where he said the courts are appropriate. On the first page he said the courts are inappropriate to deal with this. Of course judges are not scientists but that is not their function. The court function is to infuse a certain amount of commonsense into these expert, superexpert, opinions. They also have important functions

STATEMENT OF THOMAS I. EMERSON, YALE UNIVERSITY SCHOOL OF LAW, NEW HAVEN, CONN.

Mr. EMERSON. First of all I would say that I disagree very strongly with all three of my colleagues on the panel here that the first amendment has a rather pale and feeble impact on this problem. Quite the contrary. I think that the first amendment lays down the fundamental principles on which control of this sort ought to be based and that those principles can be found in the Supreme Court decisions and should be applied in this case.

It seems to me, as I state in my paper, quite clear that the framers of the first amendment were imbued with the idea of freedom for scientific inquiry. I also state or summarize some of the Supreme Court decisions which clearly reiterate that position. I think that the doctrines which the Supreme Court has adopted do not leave the subject in such an amorphous state as has been indicated.

More specifically it seems to me that to equate regulation of scientific research with regulation of obscenity is rather ridiculous. The two issues are totally different.

Now coming down more concretely to what the doctrines of the first amendment should be, as they apply in this situation, my own theory is that the first amendment offers full protection to expression, although it does not offer protection to action. In other words, the beginning of the analysis is to attempt to ascertain to what extent scientific research constitutes expression and to what extent it constitutes action. If it is expression, it should be fully protected. If it is action, it is subject to regulaton, although that regulation must conform with due process, equal protection and other constitutional requirements.

Now as applied to DNA recombinant research, I think it is clear that an inquiry into the ideas involved, into the theories involved, and an exposition of those ideas and theories and possibilities, is fully protected by the first amendment. To take the other extreme, experimentation which involves serious physical danger to the health or safety of the community is action. Clearly for instance you move into the area of action when you attempt to prove or disapprove certain theories about nuclear energy by an experiment which threatens to blow up the city of Washington. That is action.

Marching in a parade or forming an organization, although it involves more than verbalization is nevertheless within the system of freedom of expresson. But a political assassination or throwing bricks through the White House windows, is predominantly action.

It seems to me that some experimentation must be classified as within the area of expression. Experimentation is so much an integral part of the scientific method that one cannot pursue a scientific inquiry very far without it. That is an integral part of the process. Some experimentation would be classified as expression.

But at the point when experimentation threatens seriously the physical health or safety of the community, then I think it has moved into the area of action. Now there is a large borderline area in between which I won't attempt to delineate. I don't know enough about the facts to say very much more about it.

of the Federal government to preempt this field would lead to serious and widespread infringements upon freedom on inquiry.

IV.

One further aspect of the First Amendment problem remains to be noted. The Supreme Court, as a condition to sanctioning legislation which impinges on First Amendment rights, has usually insisted upon adherence to very strict procedural standards. Thus it has held that restrictions can be enforced against the exhibition of motion pictures alleged to be obscene, against the holding of a meeting which may result in violence, against the sellers of allegedly pornographic books, and the like, only where procedures for assuring adherence to First Amendment requirements are carefully maintained.[10]

In the case of DNA research, again, it is not possible for me to spell out at this stage precisely what procedures would be constitutionally required. In general they would have to be the least burdensome compatible with workable regulation. More specifically, two examples of the kind of process necessary can be mentioned. First, some form of rapid and effective court review, both of the regulations issued and of individual decisions made under regulations, would clearly be mandated by the Constitution. Second, some procedure for utilizing experts and other non-partisan scholars in the decision making process, and for assuring that decisions will be made by institutions with a sensitivity for freedom of expression, would be essential. This is an area that should be given most careful consideration.

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10. See, e.g. Freedman v. Maryland 380 U.S. 51 (1965); Carroll v. President and Commissioners of Princess Anne, 393 U.S. 175 (1968); Marcus v. Search Warrants, 367 U.S. 717 (1961). See also Speiser v. Randall, 357 U.S. 513 (1958).

detrimental to First Amendment rights. As the Supreme Court said in Buckley v. Valeo, involving the constitutionality of the Federal Election Campaign Act:

> "Even a 'significant interference with protected rights of political association' may be sustained if the State demonstrates a sufficiently important interest and employs means closely drawn to avoid unnecessary abridgement of associational freedoms".[8]

The question then becomes, what constitutes "compelling reasons" for governmental regulation of DNA research. Some possible reasons can immediately be marked off as not compelling, in the constitutional sense, though they may be compelling as the basis for decision by individual citizens. Religious, moral or philosophical arguments that man should not probe too far into the established order of nature would, I think, fall within this category. For the government to base controls on these grounds would run counter to the basic premises of a system of freedom of expression. This, I take it, is a lesson of such cases as Griswold v. Connecticut, invalidating a State law prohibiting the use of birth control devices; Roe v. Wade, upholding the right to an abortion in the early stages of pregnancy; and Stanley v. Georgia, striking down a State statute which made it a crime to read or see obscene materials in the privacy of one's home.[9] The religious or moral views of one segment of society should not be allowed to infringe upon freedom of inquiry.

From the other end of the spectrum, some reasons are clearly "compelling". Experiments which can be plainly shown to pose a serious physical hazard

8. 424 U.S. 1, 25 (1976). See also Sheldon v. Tucker, 364 U.S. 479 (1960); Hynes v. Mayor of Oradell, 425 U.S. 610 (1976); Shapiro v. Thompson, 394 U.S. 618 (1969).
9. 381 U.S. 479 (1965); 410 U.S. 113 (1973); 394 U.S. 557 (1969).

however, that experiments which pose a serious threat to the physical health or safety of a community, must be classified as action. Such conduct is analogous to the use of violence against persons or property in a demonstration, or the throwing of rocks through the windows of the White House. The physical element of the conduct is the paramount concern, and the conduct therefore falls into the realm of action rather than the expression of ideas.

On this analysis, the broad search for information about DNA, the formulation of hypotheses, the exposition and discussion of theories and methods would constitute expression, and be fully protected under the First Amendment. Thus the government could not prohibit, regulate or discourage in any way DNA research on the ground that mankind ought not to be pursuing ideas about ways to develop new forms of life. On the other hand experiments that presented a substantial and serious danger to the physical health and safety of the surrounding population could be subject to regulation without infringing the guarantees of the First Amendment. Only the requirements of due process, equal protection and other constitutional provisions would be applicable to such regulation.

III.

If we seek to ascertain the constitutionality of government regulation by more orthodox theories of the First Amendment, several possible doctrines are available. One is the classic clear and present danger test. Under this doctrine the issue would be whether the DNA research involved created a clear and present danger of a serious evil that the

it repeated:

> "Our courts...have not failed to apply the First Amendment's mandate in our educational system where essential to safeguard the fundamental values of freedom of speech and inquiry and of belief."[5]

Thus we start with a strong commitment to the principles of free inquiry and a heavy presumption against any form of governmental interference.

II.

There are several ways to approach the more specific problem of applying the First Amendment to governmental controls over recombinant DNA research. My own theory of the First Amendment, which I call the full protection theory, derives from the "absolute" position taken most prominently by Justices Hugo Black and William O. Douglas. It holds that one must first determine whether the conduct involved is "expression", which is covered by the First Amendment, or "action", which is not. If the conduct is found to be "expression" then it is fully protected by the First Amendment against any form of governmental regulation or interference; if the conduct is "action" it is not protected by the First Amendment, though any governmental regulations must conform to the due process clause, the equal protection clause and similar constitutional provisions. It should be noted at once that the Supreme Court has never accepted this full protection theory. Nevertheless I believe it is the only sound analysis and that its use here will throw a helpful light on the issues now before us.

The first question, therefore, is whether the conduct involved in DNA research constitutes "expression" or "action". It seems to me that the development or exposition of theoretical ideas about DNA and other genetic materials and processes is clearly expression. Such conduct

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5. 393 U.S. 97, 104 (1968). See also Tinker v. DesMoines Independent Community School District, 393 U.S. 503 (1969); Healey v. James, 408 U.S. 169 (1972).

I.

There can be no doubt that the First Amendment provides extensive protection to freedom of scientific research. It declares that "Congress", and that term includes all branches of government, "shall make no law...abridging the freedom of speech, or of the press, or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances". Although phrased in somewhat narrow and specific terms, the First Amendment undoubtedly was intended to, and certainly has been interpreted to, forbid the government to intrude upon all forms of expression. It was designed to maintain an effective system of freedom of expression in the United States. And freedom of scientific inquiry is surely one of the fundamental elements of a system of free expression.

As to the intention of the framers of the Constitution, I have recently had occasion to summarize their views with respect to the function of the First Amendment in the following way:

> "The process is essentially the method of science. The theory of freedom of expression, indeed, developed in conjunction with, and as an integral part of, the growth of the scientific method. Locke, following Hobbes, based his philosophical and political theories on the premises of science. And the proponents of free expression were all men who, in the broad sense at least, put their faith in progress through free and rational inquiry. Hence the process they envisaged operates upon the same principles as those that guided the men of science: the refusal to accept existing authority; the constant search for new knowledge; the insistence upon exposing their facts and opinions to opposition and criticism; the belief that rational discussion produces the better, though not necessarily the final, judgment. This process did not ignore prior knowledge or opinion, but it did insist upon the responsibility of the individual to challenge such opinion and upon the obligation of all to make reasoned conclusions based upon the evidence."[1]

1. T.I. Emerson, Colonial Intentions and Current Realities of the First Amendment, 125 U. Pa. L. Rev. 738, 741 (1977).

THOMAS I. EMERSON

Lawyer, born Passaic, N.J., July 12, 1907; son of Luther Lee and Wilhelmina (Runft) E.

A.B.,Yale, 1928, LL. B. 1931, M.A. 1946.

Married Bertha R. Paret, October 9, 1934 (deceased 1958); Children -- Joan Paret, Robert Madden, Luther Lee; married second wife, Ruth B. Calvin, May 27, 1960.

Admitted to the New York bar, 1932; Associate with the law firm of Engelhard, Pollack, Pitcher and Stern, New York City, 1931-1933; Assistant Counsel, National Recovery Administration, 1933-1934; Principle Attorney, National Labor Relations Board, 1934-1936, Assistant General Counsel then Associate General Counsel, 1937-1940; Principle Attorney, Social Security Board, 1936-1937; Special Assistant to the U.S. Attorney General, Department of Justice, 1940-1941; Associate General Counsel, Office of Price Administration, 1941-1943, Deputy Administrator for Enforcement, 1943-1945; General Counsel, Office of Economic Stabilization, 1945; General Counsel, Office of War Mobilization and Reconversion, 1945-1946; Professor of Law, Yale, 1946-___, Lines Professor of Law, 1955.

Visiting Professor, London School of Economics and Political Science, 1953-1954; Visiting Professor, Brookings Institution, 1960-1961; Guggenheim Fellow, 1953; Fulbright Fellow, Japan, 1974-1975; Member of National Lawyers Guild (president 1950-1951).

Author: Political and Civil Rights in the United States (with David Haber and Norman Dorsen), 1952, 3rd edition., 1967; Toward a General Theory of the First Amendment, 1966; The System of Freedom of Expression, 1970. Contributor to professional periodicals. Home: 2271 Ridge Road, North Haven, Connecticut 06473 Office: Yale Law School, New Haven, Connecticut 06520.

Beyond the public health question, however, beyond the public health hazards, are other fears, fears that I have, fears arising from the suspicion that scientists are probing too deeply into an area where we ought not to tread.

It is this that principally concerns me. I am more bothered by nuclear transplantation than I am by DNA recombinant molecule research. The day is near when it will be possible to remove eggs from a human female, remove the nuclei of those eggs, and replace them with somatic cells from another adult, male or female, then implant these artificially fertilized eggs, these renucleated eggs, into any female.

We are close to being able to clone human beings. But as Leon Kass has said, among sensible men the ability to clone a man would not be sufficient reason for doing so. I do not think any scientists should be allowed to proceed as if he had a right to engage in this sort of experimentation.

Nor do I think that anyone should be given a right to its presumed benefits. For example, it will be technically possible for a woman to have a child of either sex as she prefers. That raises the question, is there not a public interest involved in this? If the question is then to be decided individually, this is likely to be determined by the fashions of the day, and if the women who produce these eggs are allowed to decide for themselves whether they will have a female child or a male child, then clearly we might end up with a population that leaves something to be desired.

In other words, I am suggesting once again that the bearers of these eggs ought not to be able to determine for themselves. It is not simply a right on their part.

Mr. THORNTON. You suggest that there is a greater public interest in determining the sex of a child than there is whether a fetus will be allowed to continue to exist?

Mr. BERNS. I want to make the point that there is probably a public interest in a population composed approximately equally of men and women.

Mr. THORNTON. You did rely on the decision of Rowe against Wade in signifying there was no public interest in whether a woman should have the right to bear a child. I wondered how you think there might be a public interest as to the sex of the child.

Mr. BERNS. The public interest is more clearly involved in the latter example.

Mr. THORNTON. In the sex of a child?

Mr. BERNS. Yes. In the question of the sex of a child.

Mr. THORNTON. I wanted to understand that.

Mr. BERNS. I wanted to state no opinion on the question of abortion. I merely wanted to say here that the interests of the United States is better served by having a population composed approximately of half and half men and women.

Mr. THORNTON. I think it is good that a balance be maintained. [Laughter.]

Mr. BERNS. The interesting thing is that naturally that balance is maintained, but if we are going to have babies without sex it is entirely possible to have a population, as the fashions determine, of one or another sex.

That is technically possible now.

Mr. THORNTON. I felt it was appropriate to highlight that question.

form of speech and if so, whether it is protected by the first amendment.

If these questions had been raised in the past the answers I suspect would have been yes to both of them, in the United States, that is.

In the United States there has been no fear of science. On the contrary, the country was understood by the men who founded it to depend on science. It was the discovery of the new science of politics—that is a quoted statement—that according to Hamilton in the 9th Federalist made our society possible.

By the Constitution written by the founders, Congress is endowed with the power to promote the progress of science and useful arts by securing to authors and inventors the exclusive right to their writings and discoveries. The motto on the great seal of the United States which we can see on every dollar bill is novus ordo seclorum, a new order of the ages.

That order depended on science, the new moral and natural sciences. And these sciences were understood to be fully compatible with each other. The philosophers who expounded their principles promised the relief of man's estate on this Earth and that promise has been largely fulfilled in the United States.

The assumption underlying this new philosophy was this: What is good for science is good for society. Since absolute freedom of inquiry was good for science, it followed that absolute freedom of inquiry was good for society. Specifically for the United States.

This opinion is still held by scientists. Perhaps it is held by a majority of scientists. For example, Bernard Davis of the Harvard Medical School in the report of this subcommittee is speaking to the subject of DNA recombinant molecule research. He said he appreciated the necessity to be vigilant in our concern that knowledge not be misused, but he went on to warn that such vigilance is "a threat to freedom of inquiry, and I believe a threat to human welfare."

That is on page 259 of the report. Still, society has begun to have doubts concerning the net benefits of science; more significantly scientists themselves have begun to have doubts. I direct the attention of the committee to the remarks of Robert Sinsheimer, Cal Tech biologist. He says that scientists have had "the rare luxury to pursue truth, unhampered by conflicts of compassion." (Report, p. 249.)

That is an interesting statement. He then says that caution has been "an unfamiliar virtue," and has been subordinated to "boldness and curiosity."

He wonders whether the time has not come to reverse this. I suspect the answer is yes, it is indeed time to be cautious rather than bold. I say this fully cognizant of what is surely true, namely, that there will be benefits from further research into DNA recombinant molecules.

It is time to be cautious and, like Professor Barron, I see nothing in the first amendment to forbid Congress from expressing this caution in legislation. Like all scientific inquiry, DNA recombinant molecule research is a form of research but this fact alone does not mean that it is necessary—that it is necessarily protected by the first amendment, not to the extent to which scientists sometimes contend.

If Jefferson is accepted as our guide to the meaning of the first amendment, we can say that of all the forms of speech that deserve

fessor Berns is presently from the Department of Political Science, the University of Toronto and is an outstanding Constitutional authority.

[Biographical sketch of Mr. Berns follows:]

WALTER BERNS

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Educational background: B.Sc., University of Iowa, 1941; Reed College, 1948–49; London School of Economics and Political Science, 1949–50; M.A., University of Chicago, 1951; and Ph.D., University of Chicago, 1953.

Academic awards, honours, prizes: Carnegie Teaching Fellow, 1952–53; Rockefeller Fellow, 1965–66; Fulbright Fellow, 1965–66; Guggenheim Fellow, (declined), 1965–66; and Clark Distinguished Teaching Award (Cornell University), 1969.

Research grants: Earhart Foundation, 1969, 1972, for work on freedom of speech, and United States Department of Justice, Law Enforcement Assistance Administration, for work on capital punishment (1975–76).

Teaching appointments: Assistant Professor of Political Science, Louisiana State University, 1953–56; Assistant Professor of Political Science, Yale University, 1956–59; Associate Professor and Professor of Government, Cornell University, 1959–69; Lecturer, Salzburg Seminar in American Studies, 1959; Charles Evans Hughes Professor of Political Science (visiting), Colgate University, 1970; Visiting Professor of Political Science, University of Toronto, 1969; and Professor of Political Science, University of Toronto, 1970 to present.

Major consulting experience: Advisory Board, National Institute of Law Enforcement and Criminal Justice, 1974–76.

Administrative experience: Chairman, Department of Government, 1963–67.

PUBLICATIONS

A. Books

Freedom, Virtue, and the First Amendment (Baton Rouge: Louisiana State University Press, 1957). Paperback edition, 1965.

As joint author, Essays on the Scientific Study of Poltics (New York: Holt, Rinehart, and Winston, 1962), Herbert J. Storing, ed.

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2. "Freedom and Loyalty," The Journal of Politics, Vol. 18 (February 1956), pp. 17–27.
3. "On Robert Dahl's Important Questions", The American Political Science Review, Vol. 52 (September 1958), pp. 830–833.
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9. "Law and Behavioral Science", Law and Contemporary Problems, Vol. 28 (Winter 1963), pp. 185–212. (This issue of Law and Contemporary Problems has been published as a book, Hans W. Baade (ed.), Jurimetrics (New York: Basic Books, Inc., 1963).

equally distinguished opponents are right concerning the merits of the DNA controversy.

One of the reasons for protection for freedom of discussion is that special protection must be given to those constitutional procedures which provide for orderly change in society. In this context, the question is: should the symbolic lanaguage of free inquiry be used to authorize irreversible changes in the biological order of things? Putting the DNA controversy in First Amendment terms reminds us of similar, but by comparison more trivial, questions affecting the political order.

Traditionally, one of the most difficult of First Amendment problems has been the extent to which the constitutional guarantee of freedom of expression protects those who, if they achieved mastery of the political order, would deny such freedom of expression to all others. This has been the challenge which the Communist cases presented to the Supreme Court. And if those cases are thought of as a unit, I think it will be seen that only when it was clear to the popular imagination that the Communist danger to the society was a minimal one did the Supreme Court start according full First Amendment protection to those prosecuted under the anti-Communist legislation.

The problem of how a free society should deal with totalitarian parties with respect to allowing such parties to exploit the institutions of a free society in an effort to destroy it has been a continuing challenge to liberal political theory. In my view, the DNA controversy presents an even more difficult challenge. Even if totalitarian parties do achieve success and do abolish the vital heart of the liberal democratic state, the traditions and procedures of free speech and free press, revolution is still possible. Even in the most repressive state rebellion is possible. Budapest 1956 did occur. In politics if a sufficient combination of bravery and desperation is present, there is always the possibility of revolution and change. But in biology, if the critics of DNA research are correct, rebellion may not be possible. In the new world of DNA research, people like George Wald say that ultimately no revolution may be possible. What is done will not be able to be undone.

I am not at all sure that the traditional tools of First Amendment doctrine are adequate for the grandeur and the enormity of the issues involved in this controversy. The speech/action dichotomy and the clear and present danger doctrine are traditional tools of First Amendment analysis. But an attempt to make a close parallel between hypothesis and experiment in science and the traditional separation between speech and action in constitutional litigation is, in my opinion, hardly likely to be a fruitful one. Functionally, "action" is a social evil about to be accomplished. Are all experiments to be considered "speech" except the experiment that does in fact produce the indestructible humanoid robot? Such regulation is no regulation.

Similarly, the clear and present danger doctrine requires an assessment that the danger to be feared is about to occur. But at least such prophecies when they are put in the hands of judges are difficult enough when the problems at issue involve delicate matter's of social and political analysis and adjustment. But at least such matters bear some kinship to the legal problems for the resolution of which judges are trained. But in matters involving prophesying the ultimate achievement of DNA recombinant molecule research judges will be found wanting in terms of expertise. By training the judiciary is particularly unlikely to have the requisite scientific background and knowledge which would make them desirable arbiters of such problems. Similarly, as a group they are probably too much of an elite to have their ear on the common pulse in terms of providing reliably representative societal reaction to the merits of the controversy.

If a group of non-expert decision makers is wanted for deciding the kinds of living organisms which science may permissibly seek, then perhaps in a democratic society the best roll of experts is the voters' roll.

In summary, in matters as especialized, controversial, and important as the DNA recombinant molecule issue, I think a number of basic propositions should be kept in mind:

First, claims of pure scholarship and an unfettered right to communicate have rarely been dealt with by the Supreme Court in absolutist terms. Illustrative is the Court's approach when the Belgian scholar and Marxist Georges Mandel sought entry to the United States, but as a Communist was denied admission. The claims of free inquiry were given serious attention by the Court but in the end the traditional leeway accorded to the federal government with respect to the admission of aliens prevailed and Mandel was denied admission. In other

particular community? A pragmatic inquiry will be the real touchstone of decision in such cases, and I do not think it can be otherwise.

Fourth, if traditional first amendment tests are going to be used to resolve the question of the continuation of DNA research, I think it is better to use as clear a balancing test as possible.

The identification of the issues involved is much more likely to become visible if we do not pretend that the symbolic force of the first amendment is very heavily with one side and against another. This is not a contest between Galileo and the know-nothings. It is a problem of how many people in society should share in decisions which might reshape the nature of life.

If the problem is presented in that fashion, then I think it is revealed in its true first amendment significance. If the first amendment exists to maximize participation by all the citizenry in all the decisions which affect their future, then we should be wary of arguments which in the name of free inquiry are likely to move society and life itself in a particular direction beyond effective recall by any popular referendum.

In short, legislators are wise to be concerned that too much easy and ill-considered legislation may result in crippling research that might provide dramatic advances in the cure and treatment of disease. One does not err in giving the claims of free inquiry enormous scope.

But a claim of free inquiry by science should not be used as an obstacle to shield from oversight and participation by the electorate at large ultimate decisions which go to matters of such grandeur as the revision and creation of life.

Such matters should not be reserved solely for decision by scientists. To describe these issues in first amendment terms, it must be understood, does not in itself make a case for exclusively reserving them for scientific decisionmaking. There is, in my opinion, no basis in first amendment case law for such a conclusion.

Similarly, approaching the DNA controversy in terms of the first amendment should not be interpreted as reserving ultimate decisions as to the future of such research for the judiciary. In my view, the primary judgment in setting parameters for such experimentation should be at least at the outset a matter of legislative judgment, if it is deemed that legislation is necessary.

If thereafter either science or a section of the citizenry feels that the exercise of the legislative judgment has done violence to some fundamental human right, whether that right involves the freedom of the intellect or the security of the person, the courts are then appropriate parties to resolve the conflict.

But they are appropriate bodies to resolve this conflict only if we realize that in this area judges, like the rest of us, will write on a fairly clean slate.

In sum, with respect to the DNA controversy—in my view, at this point—the first amendment has no favorites. There is as much case law to support the proponents of the research as there is to support those who would regulate it.

Thank you very much.

Mr. THORNTON. Thank you very much for a clear analysis and a good summary of the paper which you had prepared and submitted.

tinguished opponents are right concerning the merits of the DNA controversy.

One of the reasons for protection for freedom of discussion is that special protection must be given to those constitutional procedures which provide for orderly change in society. In other words, in my view, one of the reasons we give such special and justifiable attention to first amendment freedoms in our society is because that is the structure for change.

We are concerned about any obstacles to that kind of change. In this context, the question is: Should the symbolic language of free inquiry be used to authorize irreversible changes in the biological order of things? Putting the DNA controversy in first amendment terms reminds us of similar, but by comparison more trivial, questions affecting the political order.

Traditionally, one of the most difficult of first amendment problems has been the extent to which the constitutional guarantee of freedom of expression protects those who, if they achieved mastery of the political order, would deny such freedom of expression to all others.

This has been the challenge which the Communist cases presented to the Supreme Court. And if those cases are thought of as a unit, I think it will be seen that only when it was clear to the popular imagination that the Communist danger to the society was a minimal one did the Supreme Court start according full first amendment protection to those prosecuted under the anti-Communist legislation.

The problem of how a free society should deal with totalitarian parties with respect to allowing such parties to exploit the institutions of a free society in an effort to destroy it has been a continuing challenge to liberal political theory.

In my view, the DNA controversy presents an even more difficult challenge. Even if totalitarian parties do achieve success and do abolish the vital heart of the liberal democratic state and the traditions and procedures of free speech and free press, revolution is still possible.

Even in the most repressive state, rebellion is possible. In politics if a sufficient combination of bravery and desperation is present, there is always the possibility of revolution and change. But in biology, if the critics of DNA research are correct, rebellion may not be possible. In the new world of DNA research, people like George Wald say that ultimately no revolution may be possible. What is done will not be able to be undone.

I am not at all sure that the traditional tools of first amendment doctrine are adequate for the grandeur and the enormity of the issues involved in this controversy. The speech/action dichotomy and the clear and present danger doctrine are traditional tools of First Amendment analysis. But an attempt to make a close parallel between hypothesis and experiment in science and the traditional separation between speech and action in constitutional litigation is, in my opinion, hardly likely to be a fruitful one.

Functionally, "action" is a social evil about to be accomplished. Are all experiments to be considered "speech" except the experiment that does in fact produce the indestructible humanoid robot? Such regulation is no regulation. We have to wait until that point.

Similarly, the clear and present danger doctrine requires an assessment that the danger to be feared is about to occur. Such prophecies

JEROME A. BARRON

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Author: Books (with Donald Gillmor) Mass Communications Law, Cases and Comment (West Publishing Co.) 2d ed., 1974; Freedom of the Press for Whom? (Ind. University Press (1973); (with C. Thomas Dienes) Constitutional Law: Principles and Policy (Bobbs-Merriell (1975)). Articles include "Sunday in North America," 79 Harv. L. Rev. 42 (1965); "Access to the Press—A New First Amendment Right," 80 Harv. L. Rev. 1641 (1967); "An Emerging First Amendment Right of Access to the Media?" 37 Geo. Wash. L. Rev. 487 (1969); "The Ambiguity of Judicial review," 1970 Duke Law Journal 591; (with Arthur S. Miller) "The Supreme Court: The Adversary System and the Flow of Information to the Justices: A Preliminary Inquiry," 61 Virginia L. Rev. 1187 (1975). Home: 2530 Trophy Lane, Restin VA 22091. Office: 720 20th St. NW., Washington, D.C. 20052.

STATEMENT OF PROF. JEROME A. BARRON, NATIONAL LAW CENTER, GEORGE WASHINGTON UNIVERSITY

Mr. BARRON. Mr. Chairman, first of all I would like to say I am not an expert in DNA. If there is any reason for my being here it is just to give some reflection to the question of what first amendment protection means in terms of scientific research.

It is from a first amendment perspective that I will be talking to you this morning.

When an issue of social policy becomes a sufficiently intense matter of controversy, some effort is usually made to identify its constitutional status in hopes that the controversy will therefore somehow be stilled or resolved.

But when a matter of novel and difficult social policy must be addressed in constitutional terms, it should be recognized that the battle lines are really not very much altered by the shift from a scientific and/or ethical vocabulary to a legal or constitutional one. So it is with the question of whether the first amendment protects from governmental regulation the issue of DNA recombinant molecule research.

You quoted Dr. Max Tishler to the effect that society is no longer willing to accept the proposition upon which scientific research is based: "The pursuit of knowledge is justified wherever it may take us."

Whether society has even been so tolerant is, I think, a matter of some doubt. But, let's give society the benefit of the doubt. An issue not quite so large but somewhat related is: Has American constitutional law accepted the idea that the pursuit of scientific knowledge is protected wherever that pursuit may lead?

Occasionally the first amendment has received a sufficiently broad interpretation from the Supreme Court which might suggest there is blanket protection against governmental restraint for DNA research

we would immediately know the risk is very small, because any change we make has already been happening.

So this sort of experiment would be extremely important to get started on fairly quickly, to assess what is likely to happen in the future. That is not done often enough in these technologies. It has not been done early enough in the nuclear technology.

Mr. DYSON. I would just like to put on the record the fact that it is not just getting Nobel Prizes that drives science at all. I think it plays a very much smaller part than many people believe. The book Jim Watson wrote about the double helix is an admirable portrait of Jim Watson. It is not an excellent picture of the average scientist by any means.

I have in mind myself very strongly one of my closest friends who had a 6-year-old daughter who died of polio just one year before the polio vaccine became available. I think that is what we have to think of when we talk about putting the brakes on research.

Mr. THORNTON. I think it is easy to overstate the immediacy of some benefit which might be achieved. Yet, I have the impression that if we are to really tackle the causes of such things as cancer, then an understanding of how cells work, why they lose the ability to work properly, why something in there goes wrong, maybe some of the genetic codes that keep them from replicating fail to work, this kind of knowledge might have unforeseen results. It might help us to identify the questions that need to be asked.

And, like the risk, these benefits are extremely difficult to quantify. And the benefits usually are unexpected, just as the risks are often unexpected.

I want to thank each of the panelists for your very fine testimony and contribution to the course of this hearing. It has been a pleasure being here with you. We would like to invite you to share with us such further thoughts as you may have in connection with our written questions and anything you would like to add.

This hearing is now adjourned.

[Whereupon, at 12:20 p.m., the committee was adjourned sine die.]

mittee did not want to pass on the technical issues, it was quite clear that the question of authority was the message mainly being discussed.

There was a unanimous recommendation. They felt by and large on the technical issues they had some confidence in the particular department of MIT and Howard, largely I think due to the openness with which the testimony was given by the particular university members, and there was enough dissent in the university to raise all the adverse comments, to the degree the city committee could not in fact assess.

Also the committee seemed to realize that it was a national and international problem, which this local committee could not begin to start to address. And so they explicitly excluded themselves from addressing the scientific issues in deteail.

Mr. THORNTON. Thank you.

Mr. Dyson.

Mr. DYSON. In Princeton there has been absolutely no attempt by anybody to suppress dissenting opinions. On the contrary we have sought them out. As far as I know, that is true in several other places.

Dr. MICHAEL. I would not for a moment argue that the attempt is explicit. It is part of the arrangement, the collegial arrangement that operates in the university culture. It is a subtle business, but it operates. It usually doesn't involve arm twisting among peers. However, sometimes it operates with a good bit of arm-twisting innuendo when younger colleagues are involved who do not have tenure or control of their funds. It is something to be added to the picture.

Mr. THORNTON. I would like to ask a couple of questions which may not require a great deal of comment.

Do any of you know of anybody who has attempted to conduct a formal analysis of risk-benefit with regard to recombinant DNA research? We were not aware of such a study, and did not want to overlook the possibility that someone might be engaged in such a study.

Are there some suggestions that you might be able to give us with regard to this issue. I take it all of you would be willing to make that suitable to this kind of evaluation?

You may want to respond to this question in writing. If you do have any thoughts or comments now we would be pleased to hear you. But it does seem to me we need to find some means of measuring and quantifying the problem area in which we are involved. Any suggestions would be appreciated.

I would like also to ask each of you whether you would be willing to respond to such questions in writing as may be submitted to you with regard to this issue. I take it all of you would be willing to make that kind of response.

I guess the concern that I come down to at the end of this session is whether what you have said indicates that the judgment here is going to have to be based on a collection from every available source of all available information, and then making a—hopefully educated—guess at what course of action would be a responsible balance for a period of time in the future, not for 10 years from now, not for 5 years, but for tomorrow, for next month, or whatever may be, unless we begin to accumulate more information about the subject which we are exploring.

Does anybody have any comment?

ethical issue of freedom of inquiry and the critical economic matters of the university funds and prestige.

So it might well be that one of the functions of national legislation would be to facilitate effective institutional examination by requiring, let us say, that when Federal funds were potentially involved that the votes taken on these things be by secret ballot rather than by holding up of hands.

I believe there is great need to protect dissent of this sort in traditionalized settings like universities.

As to the international issue, there is a half whimsical speculation which suggests one kind of guidance or regulation of activity, particularly for the recombinant DNA area that might be helpful. The point has been made if there were no Nobel prize to be awarded for research deriving from this kind of thing the compulsion, and intensity to get on with the exploration as soon as possible would drop precipitously.

It is true in our society humans, especially scientists, have an honest desire to know more. But scientists also share other motives that characterize this society. What they want to know, and when, and how quickly is often very much influenced nowadays by the additional desire to get the prestige and the rewards that go with getting there first. This was certainly true of heart transplant research. It was almost a scandal in that area. Being first has lots of payoff in addition to the traditional rewards of contributing to knowledge and welfare.

So one might want to think about ways of discouraging this unnecessarily intense entrepreneurial fame seeking, as a way of slowing down or cooling off the pace of research without regulating into nonexistence the motive to seek knowledge.

Mr. THORNTON. Getting back to a former President's characterization of motivation as either being a carrot or a stick, you are suggesting withdrawal of the carrot might be a more appropriate measure than to apply the stick.

Dr. MICHAEL. Yes; and, of course, this has been the American way of doing a lot of things, it seems to me, differential taxation, for example. Certainly, in this area the incentive to get research funds, and departmental growth by getting there first, has been exascerbated because we have chosen to fund universities separately. The competitive incentives for the prestige of being first, the professorial chairs that go with it, the international reputations, has been certainly a driving force pressuring each research group to get their work underway as soon as possible. In principle we could wait for the benefits, we could accumulate the knowledge more slowly, learn about the risks more deliberately, but if somebody else might beat us to the Nobel prize we cannot wait.

So how to reduce the carrot, is well worth working at.

Mr. THORNTON. How about the "no patent"?

Dr. MICHAEL. That would be as well another way to go, by all means, since one of the crucial problems we have is control of corporate laboratories and their research in this area. "No patent," both for universities and for corporations would be a disincentive.

Mr. THORNTON. The interesting thing about the no-patent issue is that it has, as have many questions, two sides.

thinks it is important, and people are willing to discuss it in broad forums.

Dr. WILSON. I would like to make a comment on how one might learn what happens in the future on this from what happens in the past.

One of the major problems with the benefit analyses which have been done is in fact you really should do a separate one for each section of society. Clearly occupational work hazard, the risk is different to the general public, and the benefit is different.

There might be other groups involved, however, and so there has not been as much decision-making done as one should have done for separately affected groups.

In this particular case of DNA it is in some cases analogous to the nuclear case where the only issues of real importance in the nuclear case are nuclear war, and perhaps the long-lived waste disposal questions. Certainly they are a political problem at most. Both these problems are international in scope. And what we do is not necessarily the most important thing as to what happens in the future.

Right at the beginning of the nuclear case there was international discussion of some of these things; there has always been international discussion of waste disposal.

On the other hand, at the present moment it is coming to the situation, I have a present concern, about the present posture of this country in these international nuclear discussions, because all my friends in Europe, some of whom are not in the nuclear industry, some are, feel this country is being rather arrogant in ignoring the opinions of people overseas, particularly on proliferation, where we are the bad guys because we proliferated, and some of the others are the good guys and haven't.

Nonethless, we started, with the best of good will, discussions with those other people. Nonetheless, we got in the situation that we make proposals that seek to be unilateral.

I think we have to follow this DNA question with extreme care. Although in the discussion there is agreement, we will get international representatives at conferences, get the sort of scientific agreement weld at the conferences on nuclear issues, when it comes to practical implementation on a domestic level, of an international issue I think we are still very far from having any institutions really available for handling it. I think the nuclear issue shows this. I think we have to develop a way to be broad enough to handle all the international issues, of which DNA is probably only the second.

Mr. THORNTON. Mr. Dyson.

Mr. DYSON. Two questions came up that I would like to answer.

First there is the question of what are the appropriate local institutions. It seems to me the institution of the Biohazards Committee has been working very well. In Princeton University there is the Biohazards Committee, which has complete responsibility for anything that is done in this area. And it is a committee that is composed of representatives from different parts of the university, the molecular biologists being quite a small minority on it, the chairman being the occupational health and safety officer of the university, whose job is protecting the safety of people irrespective of what kind of research they are trying to do.

nor that we should not do any of it, we can make progress along the way and say what we know so far.

To say one does an experiment is pretty broad. But when you get down to conditions of experiments, institutional review mechanisms, kinds of mechanisms that might be set up, and so one, I am sure the committee in Princeton has gone into some of the differences in ways one does experiments. By choosing test organisms carefully one can cut down on at least the imaginable surprises.

Mr. THORNTON. You are saying we should take all conceivable measures, perhaps, to reduce the risk.

Who makes the decision as to what risks—whether they are short- or long-term—are acceptable? Or who should make it?

You, Dr. Lowrance, wrote a book called "Of Acceptable Risk" and I believe you, Dr. Michael, wrote a paper on "Who Decides Who Decides?"

I invite each of you to address that question.

Dr. LOWRANCE. In my opinion the public does have a right to decide. By "the public" I mean yourself, Mr. Congressman, and the subcommittee, and the committee, and the various public forums that I think have grown up in quite responsible fashion in Ann Arbor and Princeton and Cambridge and San Francisco, and so on. I think the general public does have a right to be involved in deciding what chances it is willing to take in the same sense, that it has been in on deciding the chances we are willing to take in going to the Moon, and other experiments.

Dr. MICHAEL. I share that view.

Mr. THORNTON. We would like to be favored with a copy of your paper, Dr. Michael, and we will consider it for possible inclusion in the record.

Dr. MICHAEL. The problem is, at what level, which citizens get involved, in what way.

If I may refer to the freedom-of-inquiry question again, recognizing variations around that question, as Mr. Dyson does. Nevertheless in Ann Arbor this was of great concern to some university faculty. If members of the communities were to be formally involved in deciding whether or not the university should undertake the research, since they would be the people at risk, what else should they be involved in, then, in regard to what research should be done? It was not a kind of moderate position, it was either/or, regarding freedom of inquiry, and it disturbed some faculty greatly.

The scale of decisionmaking is somehow wrong for the recombinant DNA problem. It is a world problem. But today it comes down to national decisions, then local decision. Since ultimately, regardless of what a national decision might be through legislation, ultimately there are people in the community who might perhaps be—the victims of somebody coming home drunk and leaving the door open, they have got to have some part in local decisions. How that is done, I don't know. I think that is an area where we are going to have to make social innovations.

Throughout the history of the evolution of democracy we have seen—and I expect we will see here—inventions appropriate to deal with novel problematic, and highly esoteric situations. We will have to learn what those are by trial and experiment.

I want to thank each of the witnesses for your very provocative and fine statements.

One of the concerns that inescapably arises from all of these statements is why risk-benefit analysis seems to be inadequate or insufficient to help in the determination of the issues we are examining at this time.

I understand the irreversible nature of the process itself adds an important dimension. The uncertainties, because it is long range, whereas risk benefit is more applicable to short-range considerations, also aggravates the difficulty of applying such analysis systematically to the subject matter.

I guess the first question I would like to ask is whether this same pessimism regarding the utility of risk-benefit analysis would apply to all areas of basic research. What about expenditures seeking to understand and develop treatment methods for cancer, or for diseases? Is it possible or not possible to apply risk-benefit type judgments to that question?

Let's take the question of cancer and the identification of carcinogens. You have dealt somewhat with using the results of high-level tests to determine risks of low-level exposure to carcinogenic substances.

Dr. WILSON. In a certain sense I think we have already decided some of the research experiments that we would like to do, to find out which chemicals are carcinogenic. We are not going to do experiments on people, if we can help it. That is already decided. It did not take much of a decision, it was quite obvious.

One problem of applying analysis to these situations is just because we decided not to do experiments on people. So in that sense we have made an important decision. So we could classify some of the DNA experiments proposed in that category. We will make a dicision to try to avoid exposing people.

But this means, in my view, not that we should reject any risk-benefit analysis, but say it is nibbling at the edges of the problem and helping illuminate the central part of it.

We can try to identify what are the risky situations. One of the reasons that already DNA research is a matter before you, is that scientists have come up with a list of possible things they have imagined might happen, and they have not yet been able to exclude them.

In cancer research you do not usually imagine disasters. We have not been able to come up within many except for the possibility of putting out in the world a chemical which would cause such a disaster. We have exercised imagination to try to identify if there are any real hazards there which are catastrophic. When we identify them, those are the hazards to pay attention to.

There may be parts of DNA research that we can identify as extremely unlikely to be hazardous and we can go ahead.

One must bear in mind that as Dr. Lowrance said, just like the State Department, DNA risk problems are so interlocking, that you might think there is no particular hazard in a particular experiment, but a strong second-order effect brings the hazard in.

I think here we are asking just to try to isolate little bits of the inquiry so you can encompass them within the framework of one's limited understanding in a reasonable time.

in the past where human activities could produce very dangerous and also irreversible consequences.

The first example I chose was protection of atomic secrets. To let an atomic secret loose in the world I think everybody agrees is both dangerous and irreversible. In this respect, it is somewhat similar to letting a new organism loose in the world, that it could do all sorts of damage to future generations, over which we have no control.

So at the time this problem became acute after World War II the United States Government, and others, too, set up very strict regulations to deal with the problem. The Atomic Energy Commission in the United States in fact established an extremely Draconian set of rules called collectively the "Personnel Security System." And this set of rules was what governed the handling of atomic secrets.

Of course the whole idea was to establish the highest degree of containment for dangerous secrets, just as we now try to establish containment for dangerous organisms. And of course we all agreed some sort of security system was necessary, and we all agreed that we would cooperate with this as far as we could.

But the way it was done was in detail very stupid. The rules were set up in an extraordinarily inflexible fashion, so that the definition of who was a security risk was arbitrary and legalistic to the highest degree. You had endless disputes as to whether somebody or other could get cleared or not to handle secrets on the basis of criteria that seemed to the people concerned really to make no sense.

The result was, of course, that the whole system came into general contempt. And that is what I don't want to happen with recombinant DNA. So I think it is very important that when the rules are set up they be both flexible and humane, in the sense that human judgment is allowed to operate in the interpretation of the rules, so that they should not be too legalistic and pettifogging in the way the security rules were.

I must confess I have only recently, just in the last day, seen the text of one of the bills that has been proposed in the Senate for the regulation of recombinant DNA. But I must say it rather horrified me, reading the language of this bill. It reminded me very strongly of the Personnel Security regulations in its general tone. It appeared to want to try to define everything and to say in advance what is a health hazard and what is not, in the same kind of way the Atomic Energy Commission tried to define legalistically what is and what is not a security risk. So I hope you will not go that road.

I hope when the rules are set up they would leave maximum freedom to the operation of human judgment both in the way they are written and in the way they are enforced.

I mentioned in the testimony that we had in the atomic energy field the disastrous, tragic encounter between the great physicist, Robert Oppenheimer, and the officials whose job was zealous enforcement of the rules. This encounter had disastrous consequences for both sides. It ruined Oppenheimer as a public figure. That was not the worst of it. What was much more tragic was that is discredited the whole nuclear enterprise in the eyes of the public and in the eyes of the scientific community. I think the long-range consequences of this are being felt very strongly now. The fact that what I would call the good scientists were driven out of the nuclear enterprise 20 years ago by this kind of arbi-

There it was that I found and visited the famous Galileo, grown old, a prisoner to the Inquisition, for thinking in astronomy otherwise than the Franciscan and Dominican licencers thought."

My last quotation expresses Milton's patriotic pride in the intellectual vitality of seventeenth-century England, a pride that twentieth-century Americans have good reason to share.

"Lords and Commoners of England, consider what nation it is whereof ye are, and whereof ye are the governors; a nation not slow and dull, but of a quick, ingenious and piercing spirit, acute to invent, subtle and sinewy to discourse, not beneath the reach of any point the highest that human capacity can soar to. Nor is it for nothing that the grave and frugal Transylvanian sends out yearly from the mountainous borders of Russia, and beyond the Hercynian wilderness, not their youth, but their staid men, to learn our language and our theologic arts."

I am sorry I have no time to quote more of these passages from Milton. Perhaps, after all, as we struggle to deal with the enduring problems of reconciling individual freedom with public safety, the wisdom of a great poet may be a surer guide than the calculations of risk-benefit analysis.

played a great part. In that century, books not only corrupted souls but also mangled bodies. The risks of letting books go free into the world were rightly regarded by the English Parliament as potentially lethal as well as irreversible. Milton argued that the risks must nevertheless be accepted. Here are four of the salient points of his argument. I ask you to consider whether his message may still have value for our own times, if the word "book" is replaced by the word "experiment."

First, Milton was willing to suppress books that were openly seditious or blasphemous, just as we are willing to ban experiments that are demonstrably dangerous.

"I deny not but that it is of greatest concernment in the Church and Commonwealth, to have a vigilant eye how books demean themselves as well as men, and thereafter to confine, imprison, and do sharpest justice on them as malefactors. I know they are as lively, and as vigorously productive, as those fabulous dragon's teeth, and being sown up and down, may chance to spring up armed men."

Next, Milton comes to the heart of the matter, the difficulty of regulating "things uncertainly and yet equally working to good and to evil."

"Suppose we could expel sin by this means; look how much we thus expel of sin, so much we expel of virtue: for the matter of them both is the same; remove that, and ye remove them both alike. This justifies the high providence of God, who, though he commands us temperance, justice, continence, yet pours out

source of wisdom that can be helpful in handling long-range problems, namely the study of historical parallels to our present dilemmas in the past. It has sometimes been said that the risks of recombinant DNA technology are historically unparalleled because the consequences of letting a new living creature loose in the world may be irreversible. I think we can find many historical parallels where governments were trying to guard against dangers that were equally irreversible. I will describe briefly two such historical parallels and leave you to decide for yourselves whether they throw light on our present problems.

My first example is the personnel security system that was set up by the U.S. Atomic Energy Commission in the years after the Second World War to protect atomic secrets. The government rightly decided that the consequences of letting atomic secrets loose in the world were irreversible and highly dangerous. The personnel security system was designed to provide the highest degree of containment for important secrets. Unfortunately the regulations were so strict and the administration of them was so inflexible that the whole system came to be regarded by many scientists with some degree of contempt. As you all know, in 1954 Robert Oppenheimer came into collision with the officials whose job was the zealous enforcement of the rules. There was a battle, and Oppenheimer lost. I am not arguing that Oppenheimer was right. He did indeed behave arrogantly and irresponsibly

Biography.

Freeman Dyson is a theoretical physicist, born in England in 1923, a resident of Princeton, New Jersey since 1953, a naturalized U.S. citizen since 1957, member of the U.S. National Academy of Sciences since 1964. He worked at the U.S. Arms Control and Disarmament Agency and was chairman of the Federation of American Scientists in 1962-63. He served in 1977 as a member of the Princeton Community Biohazards Committee, appointed by the municipality of Princeton to give advice on the local regulation of research with recombinant DNA.

Text.

I am a physicist with no expert knowledge and no personal involvement in recombinant DNA research. If I were either expert or personally involved, I would not be eligible to serve on the Princeton Community Biohazards Committee which has spent the last three months wrestling with the problem of regulating DNA research at the municipal level. It has been a great privilege to work on this citizen's committee, which is an institution admirably suited to the job of finding out whether a local community is willing to give its informed consent to biohazardous activities within its territory.

I turn now to the subject of to-day's hearings, which is the place of risk-benefit analysis in the political regulation of science. Since I must be brief, I will also be blunt. I think

influence, and then only over a long time. That situation has changed. Science is now much more formidable, obviously, as a social impactor than when the concept of freedom of inquiry was developed. Then it was primarily a concept of conduct in the laboratory and library, not of the societal field.

Mr. THORNTON. I think it is absolutely correct that there are areas in which research has been proscribed, such as by the work of the National Commission for the Protection of Human Subjects. It seems to me that this proscription of research stems from societal judgment that in these areas a set of moral values are such that the experimentation has no benefits which are sufficient to justify a course of action which produces an unnecessarily high degree of risk.

Dr. MICHAEL. I agree. But that criteria could come to hold for other areas as well.

Mr. THORNTON. And that leads, very logically and serendipitously into the testimony of our next witness, Mr. Dyson, who does indeed go back into some historical perspectives as to the way society has dealt with these problems.

Mr. Dyson, I want to commend you for your fine paper. I think it would be very useful if you would share it with the other members of the panel and with those who are in attendance here, by summarizing it.

Without objection we will make it part of the record verbatim and ask you to proceed at this time.

[Biographical sketch and complete statement of Freeman J. Dyson follows:]

FREEMAN J. DYSON

Born: (1923) and educated in England.
Became professor of physics at The Institute for Advanced Study in 1953.
Became an American Citizen in 1957.
Intermittently consulting in various parts of the government, in particular, the weapons laboratories, the Space Agency, and the Disarmament Agency.
Served as Chairman of the Federation of American Scientists for 1962–63.
Elected member of the National Academy of Sciences in 1964.

regulating and allocating this activity, the decisionmaking process, policymaking process, operate on a scale which is insufficient to provide the required scope of control and regulation. Some of us have proposed for example that, at least in the United States, we think seriously about isolated national laboratories. This would reduce proliferation of laboratories, hence the opportunities for accidents. But as it now stands the way we allocate funds for research encourages proliferation.

What I am emphasizing here is that risk calculation about recombinant DNA, should the proliferation tendencies of the system supporting the work but we don't know how much proliferation is likely.

The last point I would like to make about the inability to adequately calculate risk-benefit here is that the benefits, as far as I have heard, are anticipated to be at least a decade or more away, whereas the risks can occur anytime now, through accidents at the laboratory; in the future, by miscalculating the consequences of deliberately introducing a chimeric entity. It is not possible to calculate these, because nobody really knows what they are dealing with. This is especially so when examining a future that far ahead. Then we are faced with estimating what people in that society value or fear.

Given the great changes in values underway in this society, as evidenced by the very fact of hearings like this and of unprecedented efforts to control research and technology applications, it is not safe at all to assume that we understand how those folks would choose to allocate their risks and benefits. I can imagine a significant portion of them being far more interested in an all-out effort to reduce the 80 percent or so of cancer calculated to be the result of environmental insult, rather than taking the additional risks involved in trying to reduce the 20 percent of remaining cancer that might be genetically engendered, which is one of the benefits proposed for recombinant DNA research.

It seems to me that part of any kind of risk-benefit effort has to anticipate values in the future and how risks and benefits might be perceived. But that kind of calculation we cannot really do. Certainly we cannot assign any numbers to it.

In closing I would simply propose, as I did in the last paragraph of my testimony, that it is critically important to recognize any risk-benefit analysis, no matter how well done, carries within it valuing biases. On issues like this it is critical that there be multiple analyses, not just by one set of experts, and that there be multiple assessments involving a wide range of stakeholders. What faces us are very large requirements for inventions in our decisionmaking, policymaking processes, in order to incorporate risk benefit types of information, along with the ambiguities, and the hopes and fears. We are moving into a situation now which is very different from the one that brought us to the ways of operating that we now use. They came from a simpler world, a less closely coupled world, one where either the risks of technology and science were not so great, or where people did not recognize they were so great. Now we have bitten the apple and we know that. We know we don't know. We have to become a learning society, recognizing that we are ignorant of what we most need to know. And that that puts us in a very difficult situation humanly, institutionally. This is because the issues we face that underly these kinds of hearings, these

STATEMENT OF DONALD N. MICHAEL, INSTITUTE FOR SOCIAL RESEARCH/CRUSK, UNIVERSITY OF MICHIGAN

Dr. MICHAEL. Mr. Chairman, let me follow the procedure of the previous speakers, and simply highlight some of the points in my paper, since, although I gather you are familiar with it, I would like to familiarize them with a few points, for the purposes of our discussion.

I associate myself completely with what I understand to be the positions of the two previous speakers. What I say will simply be variations on the same theme.

It seems to me, in assessing the utility of risk-benefit analysis for policymaking, for legislation and the like, it is critically important always to keep in mind that its utility is a product both of the risk-benefit analysis itself and the social context in which it is assessed, in which it is interpreted. This becomes particularly important in areas like the ones we are exploring here, as applied to biological research in general, and certainly to DNA research. We have to be aware as well that, in applying risk-benefit analysis, it is not only a question of the sufficiency of the risk-benefit analysis itself, but also of how it is going to be interpreted by various groups in society with different values about what is risk, what risks are worth sustaining for the benefits, and what is not worth risking.

It is also necessary to keep in mind the social setting that has been an increasingly evident one over the last few years, in our society, at least: those who see themselves at risk now insist on the right to participate in decisions regarding whether or not they should be subjected to those risks, no matter how small some independent calculations make them out to be.

This presents some very, very serious problems for our conventional forms of governance, and raises some very serious questions (that I would like to come back to) regarding the balance between freedom of inquiry, so highly valued by some groups, and others who see the public interest better met according to other criteria. The two value perspectives sometimes conflict, or certainly are going to. I think the recombinant DNA situation is a precursor of that conflict, an extremely important one, both in substance and because it will provide a basis for beginning to learn other ways of conducting ourselves in making decisions where we have ambiguous and conflicting, quantitative and qualitative information.

I would say that the general position I am taking in my paper is that, because of the social context in which risk-benefit analyses must be evaluated and used, those hoping that they will provide the means for resolving systemic problems, are doomed to disappointment. By themselves they can not do it even when they provide valid quantitative information. That is, part of the systemic problem we are dealing with, even in the best of situations, is the complex, ambiguous, and conflicting social values about what is worth risking and what is worth gaining . . . and this part can't be encompassed adequately through the methods of risk benefit analyses.

In that light I would like to add a couple further concerns about the application of risk-benefit analyses to recombinant DNA.

Dr. Lowrance pointed out there is this question of irreversibility. Once you start something with a live material the fact that you stop

5. See Todd R. La Porte, & Daniel Metlay. Technology observed: Attitudes on a wary public. Science, April 11, 1975, 188, 121-127.

6. See William Bevan. The sound of the wind that's blowing. American Psychologist, July 1976, 31(7), 481-491.

7. See the sophisticated statements pro and con limiting freedom of inquiry found in Hans Jonas. Freedom of scientific inquiry and the public interest, pp. 15-19; and R. L. Sinsheimer, & G. Piel. Inquiring into inquiry: Two opposing views, 18-19. The Hastings Center Report: Institute of Society, Ethics and the Life Sciences, August 1976, 6(4). For other straws in the wind see Culliton, B. Kennedy hearings: Year long probe of biomedical research begins. Science, July 2, 1976, 193, 32-36; and Seay, T. Stoned in Peoria. APA Monitor, June 1976, 11-12. The latter article is about Congress' refusal to fund research already approved by the National Institute on Drug Abuse.

8. Footnotes 2 and 3 are also relevant here.

9. This extraordinary and laudable social invention itself evidences the changing norms in science with regard to social responsibility. It certainly merits systematic study--which it hasn't gotten--for the deeper understanding it could provide about the social and psychological conflicts and clarities unfolding in today's science community.

10. That there was acknowledged concern about the possibility of arrogant disregard of "overly stringent" guidelines evidences another aspect of the normative and ethical disarray of this society--the same society that engendered the voluntary moritorium on recombinant DNA research.

11. Apparently the anticipated risk was perceived as too small to justify the complexities and delays associated with serious examination of the possibility of restricting the chances of accidents to regional or national laboratories analogous to Brookhaven, Argonne, NIH inhouse research itself, or the great multi-national research installation, CERN. Such facilities, if located well away from dense human habitat, would have eliminated the local issue of who is entitled to participate in decisions.

Some of us--especially Professor Max Heirich--urged the Regents of the University of Michigan to seek to join with their counterparts at other involved universities to seek funds from the federal government for a jointly shared, isolated, laboratory. Such an effort by the Regents would have been unprecedented and time consuming. But some of us urged that circumstances merited such a social invention from the group bridging the University to the larger community--the Regents being elected by the public at large. The Regents did not act on this recommendation.

12. There are growing numbers of consumerist organizations able to provide such information and knowledgable spokespersons. Scientists and engineers are prominent resources in most of these groups. Examples are Science for the People, Federation of American Scientists, Scientist's Institute for Public Information, various offspring of Nader's activities, and ad hoc groups such as those arguing against nuclear reactors.

(3) effort, money, and learning devoted to learning how to learn in these situations, to learning how to integrate persons, ideas, and actions based on new normative modes. Whatever decision making entities decide and however they do it, it will unavoidably be by way of experiment, by research and development on the norms and process of decision making.

Surely this sounds utopian, yet, as Bertrand Russel observed years ago, a utopian perspective is the only practical one in the kind of world exemplified by the recombinant DNA issue. In learning how to make public decisions involving potentially risky esoteric research we must commit the same kind of intensity of imagination, experiment, and time to learning how to conduct decision making processes as we do to learning about natural processes in the physical universe. If we do, then we can hope that, even though a particular mode of participation or outcome may not satisfy everyone, the norms developed in arriving at it will be rewarding enough to provide a sustaining sense of community while other processes evolve.

For some of us, the University of Michigan experience was a beginning of the kind of learning that could move toward realization of that hope.

Minority positions, then, must be able to command:

1. Access to sufficient information and to skilled resources to develop that information into the best case they can make. If the position is held by community representatives their technical understanding may need augmentation and they should have the funds necessary for access to supplemental information sources. Sometimes this would mean funds must be available to staff alternative technology assessments and/or social or environmental impact studies.

2. Sufficient "presence." A "devil's advocate" will not be enough. S/he is good for the conscience but usually insufficient for effective influence.[19]

3. Sufficient resources and public access to disseminate broadly their position so that others who might find it attractive will learn about it. Typically, minority positions are short of both dissemination capabilities and legitimacy. Therefore, part of the task of a decision-making entity ultimately responsible to the public interest should be to ensure its minority positions are supplied with both.

In conclusion

One fact is clear in all of the swirling ambiguity of positions and counter-positions about the state of society and what needs to be done about it: we are too ignorant of our own condition and its potentialities and problems to engineer our way into the future either materially or socially--we cannot get there the way we got to the moon. Instead, we must learn to create a new set of norms, values, and supporting behaviors that will allow us to continue to be a learning society, learning where we think we are;

new procedures will initially work well even if it were clear what "well" means--which it certainly isn't. However, whatever else is to be sought, a primary condition to be met is insuring that learning will occur that leads to improvements. In Roland Warren's words, "We need to find ways of channeling change which will assure that you and I will reach the optimum agreement possible, but that our remaining disagreement will neither immobilize us nor result in our destroying each other and those around us."[15] Some aspects of decision making that require experiment and learning follow.

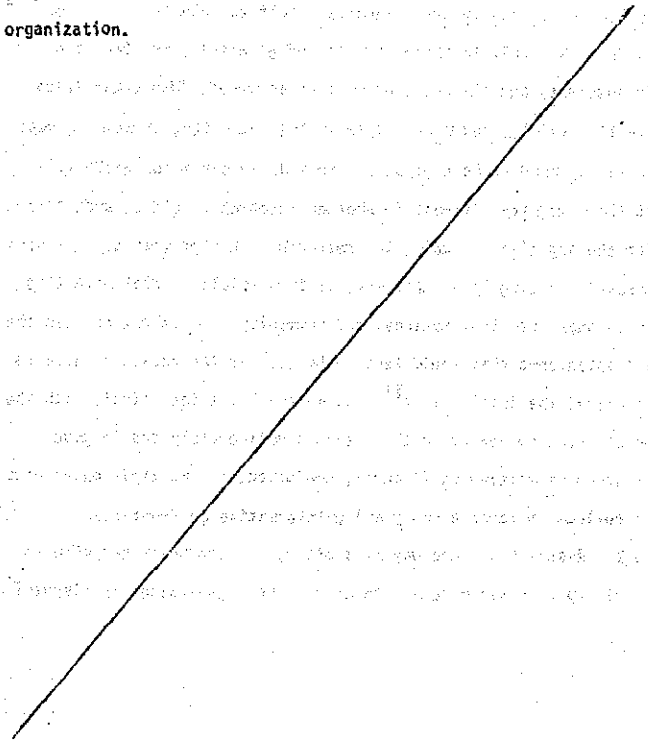
How are decisions to be arrived at? By consensus? By vote? By referendum? By what proportion? How is information to be presented and evaluated? According to a norm of advocacy or collaborative synthesis? Such questions bear not only on decision making procedures but on the proportional composition of decision making groups. Whether decision making entities in fact set policy and operations or whether they merely make recommendations to other entities that make the decisions would be additional considerations. Anticipation of how these considerations will be dealt with will influence decisions and actions associated with Steps 1 through 3.

It is at this stage that the various proposals come into play for combining technical and social considerations in decision making for public policy. These include such proposals as the science court,[16] judgment analysis,[17] and judicial evaluation.[18] Intriguing, hopeful--and controversial--as these are, they do not of themselves vitiate the new and difficult tasks of getting to the stage where they can be tried out: their use implicitly assumes that decisions have already been made about who

Step 3 would revolve around the question: How does the community participate in the organization's procedures by which it decides whether and how the community is to be involved in the later, risk-relevant decision process? Intensification of a recombinant DNA-type issue could make this a very real question indeed. The very social forces that produce the demand for a broader decision base also produce the demand that decisions about the "if" and "when" of that wider decision base themselves involve the participation or concurrence of the potentially wider base. The end of this seemingly infinite regress would appear to lie within the organization since it is being petitioned by outsiders and since it has the organization and traditions for making decisions about the extent to which it is willing to alter its decision process. These decisions depend on beliefs about who could act, in what kind of decision, conducted according to what procedures? They depend, too, on the process by which the organization would arrive at a decision that participation is permissable. And this process depends on the operative definitions of competence and "turf" described earlier.

However, not all the options lie within the organization: the community could seek legal redress in which case the decision about who has a right to be involved might be made outside the organization. In the Ann Arbor-University situation the Regents played a more active role than usual in deliberating about the proposed moderate risk recombinant DNA research. On the basis of their legal obligations to protect the general interests of the people of the State vis-a-vis those of the University, the Regents might have sought to have persons from Ann Arbor involved in the decision.

of community participation in the decision making process. Then, who is to be approached for this purpose? I.e., how does the community inform the organization of its intention to participate? Clearly, it must reach a person or persons who take seriously the community interest at least as a matter of public relations, hopefully, out of recognition of the institution's ethical obligation to the community. What is more, the person or persons approached must have enough "clout" within the organization to converge and hold its members' attention to the question of community participation in decisions which have been exclusively the perogative of the organization.



All claims on the right to participation will also be influenced by the focus accorded to the decisions to be made. That is, what is to be the purpose of the decision? What is its scope? How inclusive is it to be? Is the decision to be made chiefly a scientific one, or political, or ethical, or is it an operational matter? Is it to be advisory or binding? Note, too, that at least the initial focus for decision making itself depends on the perspectives and interests of those who decide who is to decide.

These examples of claims to entitlement in the decision making process are not exhaustive: their purpose is to emphasize that claims will be a function of the role of those who put them forward and that different values and norms will be involved including many that extend well beyond issues of scientific and technical competence.

I turn now from the question of what criteria would be contributive to deciding who is to be involved to the question of what steps must be carried through for there to be effective community involvement in the decision process. What must happen preceeding the decision making in order that it can be effectuated? The steps to be described are conventionally accomplished all the time and for this reason are, for the most part, unremarked on: the procedures of due process, the functions of duly constituted authority, and the linkages from that conventional scheme of doing things out into community membership are such that these steps get done more or less routinely. However, in this situation, claims on participation are problematic; participation raises profound problems for the conduct of free inquiry; and those outside of the conventional

Probably the first criterion applied would be entitlement to participation by virtue of competence. Competence as a criterion is clear enough when the issue is technical or scientific competence. However, what would constitute "competent" community participation? Usually it is assumed that whomever represents the community should be competent in the esoteric subject matter itself. Others, however, fear that persons from the community, competent in the scientific and technical issues, are likely to be scientists or engineers who, thereby, are likely to weigh their judgments by the same criteria as the more directly involved scientists. From this perspective there are other more relevant forms of competence such as the ability to sense and express the fears or hopes and the confusions of lay persons, all of which are held to be data as cogent for decision making as technical facts. Yet it is necessary that community representatives (or otherwise participatory community members) understand the scientific-technical issues enough to appreciate the technical bases for the arguments pro and con for the research. How to provide both kinds of competence is a central and unresolved problem though the growing capability of consumer information and action groups suggests the challenge is not insuperable.[12]

Another kind of competence belongs to those with formal organizational responsibility and associated skills to contribute to decisions and implement them. (Such legal or operational competences are represented at the University of Michigan by the Regents, the laboratory directors, the researchers, certain Deans, the Vice President for Research, Committee B, and so on.) What are the corresponding competences and responsibilities

are problems needing new solutions in order to agree and to act upon "who decides who decides?"

The first question we could ask is: "What is the appropriate geographic and temporal scale from which to draw the decision makers?" With chimeric biological materials it is impossible to anticipate how wide-spread will be the conseqeunces for natural life forms.[8] Therefore the appropriate decision maker pool would seem to include the whole world as well as future generations since everyone, especially future generations, may be the deliberate or inadvertent beneficiaries and/or casualties of this research. But there is no such world level decision making capability; the initial examination of the risks in recombinant DNA research, undertaken by involved scientists during a self-imposed moratorium, is as close to world scale participation as we've gotten.[9]

Lacking world scale, or even a world regional scale decision making capability, we are thrown back on the nation as more appropriate than the immediate environs around the research laboratory for making decisions that have such profound consequences over space and time. The NIH Guideline deliberations were an exceptional and on the whole admirable experiment in this direction though these lacked sophisticated studies delineating the long-term social cost and benefits of the research, in part because we know too little to do very much in this direction. Moreover, the question of who would be entitled to participate in decisions about process risk exposure in the proximate area where the research would be done was left unexamined. Instead the main emphasis was on how to balance the need to minimize risks for those outside the laboratory, against the risk that if

citizens should have a formal part in decision making about whether to undertake moderate risk recombinant DNA research; the "duly constituted authority" position was the dominant one within the University. However, the University administration and the scientists proponents for the research recognized the need for an informed community and that the University might benefit from community advice: the administration had established Committee B much earlier and the administration and the Senate Assembly financially supported the Forums. And some recommendations in Committee B's report urged community representation in the governance of recombinant DNA research: citizen members on the research monitoring committee and on a proposed "oversight committee." Membership on these follow-on committees rather than a part in deciding whether there should be research at all was, then, the University's not unconventional response to this unconventional problem. This expressed, surely, the conventional reluctance of those with the power to make decisions to diffuse their perogative. But there was another consideration that preoccupied many and will continue to as the decision challenge reoccurs: protection of the freedom of inquiry.

It is a basic belief of most University faculty members and, indeed, of educated people everywhere in the West that freedom of inquiry must not be constrained in any arbitrary manner, especially not by persons outside of the community of peers associated with the inquiry. It is, however, an increasingly challenged belief, both by some who well understand its centrality for conventional definitions of an open society and by others more preoccupied with other priorities.[7] Research in the biological and social sciences has added new intensity to the challenge.

research and to the very high priority assigned to it in this society. The challenge revolves especially but not exclusively around questions of autonomy and priority when the research is supported by public funds. Significantly, these challenges come not only from lay opinion leaders but also from vocal and accomplished scientists. Increasingly, questions are asked about what research should the public pay for (i.e., what research contributes to the public weal) and under what circumstances is scientific research, its methods, and resultant technologies appropriate for seeking answers to or dealing with the problems and possibilities of the human condition. There seems to be a substantial perhaps growing anti-technology undercurrent that, while by no means exclusively correlated with emphasis on citizen participation, may often found in close ideological association.[5]

A third challenge to the conventional decision making processes expresses itself in pervasive questioning of the legitimacy of existing organizations: that is the validity of their entitlement to make decisions affecting those outside the organization and of the processes by which they do so. The questioning includes re-examination of conventional definitions of what constitutes competency to make such decisions. Throughout society there is much distrust of large organizations. Since scientists are mainly associated with large organizations, this contributes to rejection of the image of scientists as motivated exclusively by a disinterested devotion to truth. Rejection of this image is strengthened by growing recognition that intense competition among scientists, plus heavy dependency on public funding of scientific research by the institutions supporting the scientists, result in deeply

with the laboratories and that such perfection cannot be expected to prevail given human fallibility and the unintentional inevitability that, sooner or later, some emotionally disturbed person(s) will be involved in these activities; (2) we really don't know what the consequences would be of accidental leakage into the environment because we don't know what products would be leaked and we don't know what knowledge and ignorance about the environment would be involved in coping with that leak;[3] and (3) as can now be calculated, if one disregards human fallibility it looks like the odds of accidental dissemination from a specific installation are very, very small. In sum, there are legitimate questions about just how small those odds would be in "real life" and there are very serious unanswered questions about the consequences of those low probability events if they should occur. The consequences could be enormous and herein lies a major area of concern for both scientists and nonscientists alike.

It remains to be observed that even if the likelihood of leakage is small, history amply evidences that "rare" accidents do, in fact, happen.[4] For all these reasons some in the University and some in the larger Ann Arbor community saw a compelling need to face the question of whether or not to undertake the research.

Given the problematic nature of the risks associated with esoteric research, very difficult operational issues will attend efforts to evolve and implement new decision making procedures that include the larger community in decisions about undertaking the research. To further appreciate the nature of the task it will be useful to review some of the sources of discontent with and repudiation of conventional decision making procedures, based

be expected to advance human welfare. Furthermore, all that could reasonably be done would be to minimize the risks, but risk is part of life and part of the cost of gaining new knowledge from which humankind ultimately will benefit.

An alternative response, the one that undergirds the questions that give cogency to the chapter, and one that seems to be subscribed to by growing numbers of lay citizens, would argue that: whatever level of risk is involved, those who might be victims should it become fact should have a formal part in deciding whether and under what circumstances to accept the risks.

The argument continues: Given the nature of recombinant DNA research, in principle, all citizens of the world should have a part since the consequences of accidental leaks of material from laboratories conducting that research could well be world-wide in scope. At a minimum, according to this argument, the community immediately surrounding the research environment (in this case, Ann Arbor, Michigan) should be directly involved in deciding whether the University should undertake such research, certainly when the research is supported by public funds and conducted in a publically funded organization.

To better appreciate the argument for this position and the dilemmas and difficulties that arise in attempting to transform the general logical or ethical case into operational terms it is useful to be more specific about the nature of the risks themselves in the recombinant DNA case.

Two types of risks have been delineated: process risk and product risks. Process risks pertain to the consequences of <u>accidental</u> dissemination

Who Decides Who Decides: Some Dilemmas and Other Hopes

Donald N. Michael*

December 1976

After carefully considering the situation, one part of a community seeks to undertake a scientific activity, in which it has deeply vested interests, that will put another part of the community at a problematic risk for what are believed by the proponents of the activity to be socially worthy reasons. Who, on what basis, decides whether the action is permissable? And who decides who decides when circumstances are sufficiently unconventional to raise questions about the procedures and legitimacy of conventional decision making structures and personalities? Indeed, who decides that circumstances are sufficiently unconventional to merit new decision making procedures and participants? We are faced here with what seems like an infinite regress, the result of many circumstances but especially the result of the dissolution of an accepted set of values about the good and the right and the processes for establishing and maintaining them--including norms regarding who decides who decides about what. This dissolution is importantly but not exclusively a result of science and its powerful technologies and of the influence of scientists themselves, some of whose words have helped define and extend the conflicting and transforming normative issues burdening this society, this world. Because of the pervasive and ambivalent role science and technology play in our lives an important consequence of this dissolution of shared norms and values, and of the decision making procedures that represent and reinforce them, has been to focus a variety of disparate concerns on the conduct and consequences of scientific research.

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FOOTNOTES

1. "The approaches referred to as 'risk-benefit analysis' try to quantify as many variables as possible and then calculate the balance or optimum for the situation. No matter what assumptions they embrace, such analyses are still at best comparisons of incommensurables--deaths and dollars, tumors and kilowatt-hours--and can hardly place proper values on integrity of community, personal brief, missed opportunity, beauty of surroundings, or the previousness of the human hereditary material.... In practice so far, risk-benefit analyses have been used mostly as background information. The art is so primitive that in debates, differing analyses can simply be played off against each other." William W. Lowrance. Of acceptable risk: Science and the determination of safety. Los Altos, Calif.: Kaufmann, Inc., 1976. P. 99

2. This observation is meant to apply to the contending scientist participants as well as others.

3. "Environmental science, today, is unable to match the needs of society for definitive information, predictive capability, and the analysis of environmental systems as systems. Because existing data and current theoretical models are inadequate, environmental science remains unable in virtually all areas of application to offer more than qualitative interpretations or suggestions of environmental change that may occur in response to specific actions." National Science Board/National Science Foundation. Environmental Science, 1971, p. viii.

4. Of special relevance to this last point it would seem that one risk worth attending to will be that to the future of biological research if there should be a severe accidental consequence from recombinant DNA research.

5. In this regard see my "Who decides who decides: Some dilemmas and other hopes." To be published in Stich, Stephen, & Jackson. The recombinant DNA debate. Ann Arbor: University of Michigan Press, 1977.

6. I am specifically referring here to such questions as freedom of inquiry, the priority of economic efficiency, and the place of public participation in esoteric issues.

The risk R/B carries of overconcretizing the flux of societal complexity and of reducing a sense of its endless chains of interaction is also a benefit in that it provides a focus on some of the issues. It is a vehicle for encouraging dialogue and engagement, but one that carries both the virtue and dangers that inhere in all powerful symbols.

In sum, the chief virtue of R/B analysis is a pedagogical one of sharpening the issues and thereby alerting the interested parties to those questions about risks and benefits that R/B analysis can't deal with. It provides the background against which it is clearer what and who haven't been considered and what aspects are important that can't be measured.

These assets and liabilities are heightened when R/B is applied to biology-based applications and especially to recombinant DNA. First and foremost is the intractable task of calculating the implications of potential irreversibilities in humans and the ecosystem. With living systems stoping deleterious inputs of living things does not guarantee eventual recovery from damage: the ecosystem may have been irremediably altered--including its human membership. With recombinant DNA the problem of estimating either first order risks or the risky second order consequences of benefits--is compounded. That is if the deleterious agent is accidently introduced its impact may not be detectable or traceable until its ecosystem impact is well along in time or space.

Second, whether deliberately or accidently introduced, our knowledge of ecosystemic interactions is too limited to state with certainty and inclusiveness what aspects are likely to be affected.[3]

Third, the extent of problematicalness in this area seems greater than usual. This is evidenced by the intense arguments in the knowledgable scientific community over what to measure and why in order to determine the probability of risk or benefit as well as over the probabilities themselves. And they also argue over how severe or beneficial are likely to be the outcomes.[4]

Another unmeasurable risk in the recombinant DNA case has to do with reliability of the human factor in successfully maintaining laboratory security. We know that alertness falls off in the absence of threatening situations. It's as if people act on the premise that, "Since nothing has gone wrong, nothing will go wrong." We know too that alertness and precision of behavior depend on mental health. Yet not all custodial help, graduate students, and senior researchers will be mentally healthy. We know that the chances of something going wrong will be a function of the number of laboratories involved in the activities. Yet there is no way to know how many laboratories there will be. And we know that security depends on the sufficiency of control standards to which personnel are supposed to subscribe. On none of these do we have sufficient data or theory to calculate risks. Yet such factors singly or in combination can make a profound difference. Human error is the critical factor over and over again as the recent horrendous tragedy at Tenerief Airport exemplifies.

Risk Benefit Analysis in a Turbulent Society

Donald N. Michael*

5 May 1977

Certain societal circumstances have converged in an intense, almost desperate, search for means to represent the anticipated trade offs between risks and benefits from the utilization of new scientific knowledge or technology. I begin with some of these circumstances because they both energize the search for and use of risk benefit measures and limit their validity and usefulness.

The first circumstance is that of enormous and increasing complexity. This is compounded of the impact potency of technology and the ever closer coupling of all human activities regardless of their location in geographic space or future time. The result is, in Garrett Harden's phrase, that "you can't do just one thing." Everything affects everything.

The second circumstance is the growing awareness, at least among but not limited to those creating or guiding society, of this kind of complexity and of the need to respond appropriately to its exigencies. These people include both the creators and the critics of the state of society, its knowledge and technologies, and its modes and means for evaluating social actions --such as risk/benefit (R/B) analysis--and for regulating them.

The third circumstance is increased sensitivity to the selective manner in which technological impacts distribute their costs and benefits among those who differ in socio-economic status, geographic location, and stage of life development--and this includes the life of future generations. Coupled with this sensitivity is a growing acknowledgement that a better quality of life requires better quantitative measures like R/B analysis and an emphasis on non-economic, non-materialistic, non-quantifiable aspects of the human condition.

The last circumstance is a summation of the other three. The close coupling of society (including especially its elaborate communication system) and the concern with the consequences of new knowledge and new technology intensifies and facilitates efforts by interested parties to influence the definition of the issues, the means for evaluating them, and the policies and actions proposed in light of the evaluations.

It is in this context that risk/benefit analysis displays its potential strengths and weaknesses for contributing to enlightened decision making and action taking. I begin with its inadequacies because it is in the light of these that its usefulness can be assessed.

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What we need is a flexible, interrelated analysis of the situation. I don't think one-time risk-benefit analysis serves us in this case.

Mr. THORNTON. Thank you very much.

I want to say that your paper is a very thoughtful presentation. It contains a lot of real philosophical perspective which I deeply appreciated as I read it.

In fact, I think that comment holds true with regard to each of the witnesses this morning. Each of you has brought to this hearing not merely the fruits of your expertise in your fields but also a concern about the social implications of this important question with which we are dealing.

As I listened to your presentation, and read the papers, I was struck by a point which is shared in common by each of you, about the nature of the risk of a catastrophe, "irreversible" I believe is the word you used, as contrasted with the risk which is predictable, which is a catastrophe for the people involved—the automobile accidents, the risks which can have a tremendous impact on individuals, but which are not likely to constitute a threat to society itself as a whole, as would for example the risk of war. The risk which alarmed me as a person of some years earlier age than I am now was the speculation that the first hydrogen bomb explosion might possibly ignite the oceans. If you recall, this was discussed as a significant risk at the time that the explosion was planned. Some scientists thought the deuterium in the ocean might be stimulated into a chain reaction and we might turn our little planet into a brief-lived nova, or something approaching that.

I think maybe that is a source of concern about this subject. That is, assessment of risk involving calculated exposures of lives of people who are involved in a given activity is one thing; but acceptance of a risk which without any fault of his own can affect a nonparticipant is another type of risk. I think each of you has pointed out that this is a factor that needs careful consideration.

Do you have any comment with regard to what I have said?

Dr. LOWRANCE. That is a quite correct perception.

I did mention in my prepared testimony that one characteristic of this work is that only a very small percentage of the world actually engages in the research, and for a very long time only that small percentage will have the benefit, although in the long term of course we may see large changes in society from it.

The risks and the benefits are going to be put out as sort of an impersonal good or bad which will go out upon the whole society.

These living organisms know no political or national boundaries. So even if we are not concerned for our own research, even just thinking about the global situation, Mr. Chairman, as I said, if we stopped all this research cold we would still have to worry about what is going on elsewhere, whether some entrepreneurial laboratory on the other side of the world decided to engage in these experiments.

Mr. THORNTON. You point out there is some evidence recombinant DNA transformations of life do occur in nature, at some levels. And although that is not directed in a laboratory atmosphere, as you point out it does happen.

Dr. LOWRANCE. As with other risks.

Referring to radiation, there is a fair amount of radiation in our background. We have to learn to live with it and work around it, some-

STATEMENT OF WILLIAM W. LOWRANCE, DEPARTMENT OF STATE

Dr. LOWRANCE. Thank you.

I am not in any way representing today my new employer, the Department of State, but simply speaking for myself as a private citizen interested in the problems of social risk. There is a risk associated with being part of the State Department, but I am not speaking for my employer this morning.

Mr. THORNTON. I think your Department probably deals with risks which fit into Dr. Wilson's characterization as being those risks which have an enormous effect in being a large exposure, where the probabilities have not been exceedingly high for any particular development occurring, but the size of exposure at the end demands a great deal of skill, caution and preparedness.

Dr. LOWRANCE. Also, risk tends to be highly interrelated, and what one does in one area is related in the most remarkable way sometimes to something on the other side of the world.

Mr. THORNTON. Have you found out yet what effect you have by pulling one particular string as it goes through the maze?

Dr. LOWRANCE. Having been there about 100 days, I still find some of those, much to my astonishment, in some cases, especially in dealing with problems of nuclear power and nuclear proliferation to which Mr. Wilson referred. Those strings seem to go everywhere.

Mr. THORNTON. Yes.

Please proceed. Thank you.

Dr. LOWRANCE. I will touch on a few points in my prepared statement, which the other witnesses my not have seen.

Essentially my point is that, although formal risk-benefit analysis has been useful in the past in looking at well-defined problems, I agree with Dr. Wilson that formal risk-benefit analysis can hardly be applied to recombinant DNA research, the subject before the committee this morning.

First, the term "recombinant molecule research" covers an extremely broad range of laboratory activities. I think that is illusive, in the beginning. Some of these experiments have gone on a long time; some we are beginning right now just to envision, and do not know, even the range of our imagination in this area.

Second, the long-range consequences of the various experiments are not at all well known. We have been surprised already.

As I said in my testimony, this research tinkers with the very essence of life forms. I do think it is novel, in the sense that this goes very, very deeply, and we are just at the edge of a broad range of experiments now. We do not know what the possible outcomes might be, and we don't know the probability of those outcomes. If someone says to me will I do a R–B analysis, I would say "I will be glad to do the analysis if you will give me the numbers."

I have shown others on the panel how I would draw a "decision tree." Here is a branch. On the left branch I draw a branch with three possible outcomes, and that gives an array of, say, seven final possibilities, and I would decide what the probabilities are, the utility, and know which is the most important.

To me this implies, then, that certain key experiments should be done before others, perhaps under exceedingly tightly controlled conditions, in order to gauge the variables and set the baselines. It implies that physical and biological monitoring regimes should be established. It implies that voluntary restraint should be encouraged and sophisticated institutional review mechanisms be set up. It implies that international discussions should be pursued. Most of these actions are now being taken. What is required is that the experimental proposals being developed and the findings coming out of the laboratories be subjected to flexible, iterative, ongoing analysis. Broad discussion is essential.

One distinctive feature of most of this research is that although the primary alterations made by the investigators are at a molecular level, the overall effect of that alteration may well be expressed at much higher levels of organization. This means that the evaluations must deal not only with molecular genetics but also with survivability of the test organisms outside the laboratory, with their ability to infect other organisms, with their ecological proclivities (such as the adaptability of new strains of E. coli among the flora of the human gut), and with

to feel as confident of their prognosticative abilities in this field as they would like. So while we are approaching the stage of trying to "weigh benefits against hazards", we are still back at the stage of trying to learn in the first place what the effects of these experiments might be. Except for the extreme cases, we do not know precisely either the possible outcomes of the experiments or the likelihood of those outcomes. Under such conditions of ignorance it is almost impossible to fill out a balance sheet.

Third, the recombinant nucleic acid research has several features that, especially if viewed together, make it a novel case. Genetic changes are largely irreversible and are passed on to succeeding generations. With those test organisms that survive outside of the laboratory, effects may be transmitted widely and involuntarily upon the larger public. The very process of gathering the experimental information required to make a full appraisal of the situation may in itself bring hazard.

Fourth, formal risk-benefit analysis finds best application in policy situations for which the elements of the analysis are somehow parallel to the elements controlling the real-world