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THE WHITE HOUSE
WASHINGTON

Date: 10/11/90

TO: Ede Holiday

FROM: **STEPHEN I. DANZANSKY**
Deputy Assistant to the President
and Director of Cabinet Affairs

This Bromley memo may provide some background and light on the FCCSET mandate and relationship with the DPC & EPC.

It may be useful later if we get into future "turf" battles on jurisdiction.

Steve D

THE WHITE HOUSE

WASHINGTON

DQB has seen 2/17

February 16, 1990

MEMORANDUM FOR DAVID Q. BATES

FROM: D. ALLAN BROMLEY

SUBJECT: FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING AND TECHNOLOGY

Your memorandum of February 5, 1990 concerning the structure and operations of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) is greatly appreciated. Ken Yale's participation in the first FCCSET meeting on January 24, and his subsequent conversations with Tom Ratchford on a variety of issues related to FCCSET have also been immensely helpful. Clearly, it will be a significant challenge to develop and coordinate truly national research programs from various components in several agencies. However, the success of the FCCSET Committee on Earth Sciences in the area of global change does, I believe, point the way for other areas of research and development.

Although the primary responsibility of the FCCSET is to coordinate R&D among the federal agencies, and the overwhelming fraction of the efforts of its committees will be directed toward accomplishment of this mainly technical task, the FCCSET should play a constructive policy role with respect to the Cabinet Councils. Below are some preliminary thoughts on how this might be structured; I would be pleased to discuss the issue with you in more detail, at your convenience.

The major policy role of FCCSET would be to provide expertise and analyses to the DPC, EPC, NSC, as well as the Space and Competitiveness Councils. Typically the issues would be very broad, with science and technology playing an important but subsidiary role. In many - perhaps most - cases, the FCCSET could be tasked by the appropriate council to provide analysis of a particular issue. In some cases, alternative options might be analyzed by the appropriate FCCSET committee, in response to specific requests by a council. In other cases - probably not very many - a broad issue with mainly scientific and technological content might evolve to the point of deserving consideration by a council.

What we need are effective ways for the councils to identify policy issues to be sent to the FCCSET. With some thought and planning, I believe this can be done in an operationally satisfactory manner.

Somewhat easier to conceptualize, is the process by which policy issues might originate in FCCSET and be fed into the appropriate council. As FCCSET chairman, and a member of EPC and DPC, it would be my responsibility to propose these council agenda items.

The above discussion has focussed on what I call science and technology for policy: i.e., making sure that the best science and technology (from the FCCSET) is made available in a timely, "user friendly" manner to the policy fora (Cabinet Councils). An example of this is the input of the FCCSET Committee on Earth Sciences to the DPC Climate Change Working Group.

In addition to science and technology for policy, there is also a need, in some cases, to provide policy for science and technology. This class of issues typically is not important enough - on the national scale - to earn attention from a Cabinet Council, and could be resolved directly by the FCCSET. An example of this class of issues is the setting of priority among and within areas of basic research.

I am convinced that FCCSET, properly organized and functioning smoothly, will make a significant difference in the coordination and priority setting within federal science and technology programs. This is the primary responsibility of OSTP and of FCCSET as set forth in our founding legislation. FCCSET can also be a useful adjunct to the primary policy fora, and we look forward to working with you to see that this is done in the most effective manner possible.

Document No. _____ CA

OFFICE OF CABINET AFFAIRS STAFFING MEMORANDUM

Date: 4-18-90 Due by: --

Subject: FCCSET Formation -- File memo update

From: Ken Yale

	ACTION	CONCUR	FYI		ACTION	CONCUR	FYI
BATES	☐	☐	☑	JACKSON	☐	☐	☐
DANZANSKY	☐	☐	☑	MCBEE	☐	☐	☐
ADAIR	☐	☐	☐	SCHALL	☐	☐	☐
BUCHHOLZ	☐	☐	☐	WETHINGTON	☐	☐	☑
D'ANDREA	☐	☐	☐	WILLIAMSON	☐	☐	☑
DEWITT	☐	☐	☐	YALE	☐	☐	☐
DUGGAN	☐	☐	☐	_____	☐	☐	☐
EVANS	☐	☐	☐	_____	☐	☐	☐
FARRAR	☐	☐	☐	_____	☐	☐	☐
HEIMBACH	☐	☐	☑	_____	☐	☐	☐

Comments:

OIN -
Please see me on this

THE WHITE HOUSE

WASHINGTON

April 18, 1990

MEMORANDUM FOR THE FILES

SUBJECT: FCCSET Formation

BOTTOM LINE: The Federal Coordinating Council on Science, Engineering and Technology is in the process of completing the formation of its committee structure. Actions need to be taken now to ensure appropriate coordination with the new structure.

BACKGROUND: You will recall that, at the last FCCSET meeting (March 14), Dr. Bromley asked for the names of suggested chairpersons for each committee. Since then, the membership and structure of 7 committees have been created (see attached list).

Charters are being prepared for all the committees, and they will be sent to Dr. Bromley by the end of the week. There will be a meeting on April 24 (Tuesday) of all the committee chairmen to discuss the charters and make any necessary changes. The charters will then be tabled at a meeting of the full FCCSET on April 30 for final approval. It is then planned that the charters will be published in the Federal Register, possibly with the names of the members.

Staff of FCCSET have stated that the charters will not be made available for review until the FCCSET meeting. Of course, at that time there may be no way to make appropriate changes. In addition, it is difficult to determine whether the activities contemplated by the FCCSET Committees will overlap or conflict with other interagency working group activities. Finally, absent any movement to form or convene the Cabinet Council Science and Technology Working Group, there may be a natural tendency for the FCCSET committees to take up the issues more appropriate to the Working Group.

RECOMMENDATION: The Science and Technology Working Group charter should be prepared, Dr. Bromley could announce formation of the Working Group in the FCCSET and other meetings, and meetings of the Working Group should be started as soon as possible, to show there is a viable process for taking issues to the Cabinet Councils. In addition, The EPC and DPC executive secretaries should be able to participate in the April 24 meeting to ensure adequate coordination on issues with FCCSET. We should also request copies of the charters, to ensure they do not inadvertently conflict with DPC and EPC charters and activities.

FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING & TECHNOLOGY COMMITTEES MARCH 1990

Earth and Environmental Sciences

Chairman: Dallas Peck, Director, US Geological Survey, Department of the Interior

Vice Chairmen: Erich Bretthauer, Assistant Administrator for Research, Environmental Protection Agency

Lennard Fisk, Associate Administrator for Space Science and Applications, National Aeronautics and Space Administration

OSTP Liaison Member: James B. Wyngaarden, Associate Director for Life Sciences

Education and Human Resources

Chairman: Adm. James Watkins (Ret.), Secretary, Department of Energy

Vice Chairmen: Ted Sanders, Deputy Secretary, Department of Education

Luther Williams, Senior Science Advisor, National Science Foundation

OSTP Liaison Member: J. Thomas Ratchford, Associate Director for Policy and International Affairs

Food, Agriculture and Forest Research

Chairman: Charles Hess, Assistant Secretary for Science and Education, Department of Agriculture

Vice Chairmen: David O'Neil, Assistant Secretary for Land and Minerals Management, Department of the Interior

James Benson, Acting Commissioner, Food and Drug Administration, Department of Health and Human Services

OSTP Liaison Member: James B. Wyngaarden, Associate Director for Life Sciences

REVISED 4/4/90

International Science and Engineering

Chairman: Reginald Bartholomew, Under Secretary for Security Assistance, Science and Technology, Department of State

Vice Chairmen: Fred Bernthal, Deputy Director, National Science Foundation
Philip Schambra, Director, Fogarty International Center, National Institutes of Health, Department of Health and Human Services

OSTP Liaison Member: J. Thomas Ratchford, Associate Director for Policy and International Affairs

Life Sciences and Health

Chairman: James O. Mason, Assistant Secretary, Department of Health and Human Services

Vice Chairman: David Galas, Associate Director for Health and Environmental Research, Office of Energy Research, Department of Energy

OSTP Liaison Member: James B. Wyngaarden, Associate Director for Life Sciences

Physical, Mathematical and Engineering Sciences

Chairman: Erich Bloch, Director, National Science Foundation

Vice Chairman: Charles Herzfeld, Director Defense Research and Engineering, Department of Defense

OSTP Liaison Member: Eugene Wong, Associate Director (designate) for Physical Sciences and Engineering

Technology and Industry

Chairman: Thomas Murrin, Deputy Secretary, Department of Commerce

Vice Chairman: J.R. Thompson, Deputy Administrator, National Aeronautics and Space Administration

OSTP Liaison Member: William D. Phillips, Associate Director (designate) for Industrial Technology

S&T

THE WHITE HOUSE
WASHINGTON

Date: 3-12-90

TO: KEN YALE

FROM: **STEPHEN I. DANZANSKY**
Deputy Assistant to the President
and Director of Cabinet Affairs

I have forwarded to Olin for a look at the tax policy aspects.

By focusing on S&T working groups on the broader aspects of small S&T entrepreneurs, we can preempt the bio-tech field.

cc: Olin Wethington

THE WHITE HOUSE

WASHINGTON

March 9, 1990

MEMORANDUM FOR THE BIOTECHNOLOGY WORKING GROUP of the COUNCIL ON COMPETITIVENESS

FROM: LARRY LINDSEY, Chairman, Finance Subgroup

SUBJECT: Preliminary Report

To date we have elicited the views of biotechnology experts from two very different firms. Jim Sherblom, Chief Executive Officer of Transgenic, expressed the views of a small firm which concentrates uniquely on biotechnology products. The other, Bob Fraley, Director, Plant Science Technology, Monsanto Agriculture Company, reflected the views of a large, diversified firm in which biotechnology plays a minor, albeit significant, part.

We found many of the problems faced by these two firms to be similar. However, there were significant differences in their views on a number of key policy issues. Our analysis therefore focusses on this dichotomy: general problems of the industry and unique problems of small firms. A key effect of any policy decision will be the structure of the biotechnology industry. We consider several possibilities in the conclusion.

Industry Wide Challenges

Public Acceptance and Demand for Biotechnology Products. It goes without saying that all of the incentives and regulatory relief in the world will not help an industry whose product does not enjoy widespread public acceptance. At present, the biotechnology industry faces widespread public resistance, based primarily on ignorance, but fanned by some anti-technology extremists. Furthermore, the problem of public acceptance is international in scope. We can draw several conclusions from the evidence presented on this problem.

- Federal regulatory policy has failed in its mission. Ideally, regulation should both protect and reassure the public. There is evidence that the existing regulatory apparatus goes to great lengths to protect the public. Yet, the public does not believe that approved products are safe and effective. Public acceptance of a regulated technology is inherently an economic "public good". The federal government therefore has an obligation to take positive steps to increase public acceptance of biotechnology.

- Public acceptance is likely to grow, but the next few years are critical. Young people are now being exposed to the concept and practice of biotechnology early in their educations. High school biology experiments now include cloning a gene from yeast. But, international competition is such that an unfavorable economic and regulatory environment in this country is likely to cause America to lose its technological edge in this key industry.

- The issue of public acceptance can be manipulated as a trade policy tool. The recent example of the EC banning U.S. beef is an example of what can happen to biotechnology products. Other nations can ban or create informal barriers such as labelling and inspection requirements which limit access to American biotechnology products. In the meantime, their domestic biotechnology industries can develop. These restrictions can then be removed when their domestic industries are able to withstand U.S. competition. Our trade representatives should be aware of this strategy and take aggressive action to protect foreign markets for U.S. products.

Intellectual Resources. The need for increased funding for the training of our future biologists is clear, and was recognized in the President's budget. Emphasis is also needed on adequately training students at the elementary and secondary levels. President Bush and the nation's Governors have jointly established goals, one of which is to make American high school graduates number one in math and science by the end of the century. In addition, we face a potential problem in that a significant percentage of the graduate students and professors in the biological sciences are citizens of other nations.

- The government should continue the commitment evidenced in the President's budget to encourage excellence in America's scientific education. It is incumbent upon the Congress to enact the President's Education Excellence bill, proposed last year. Furthermore, states must continue to emphasize quality and accountability of students, teachers, parents, and local school officials.

- Federal immigration policies should consider the need to retain our competitive edge in biotechnology. America has always had an open door policy to students wishing to study in American universities. Our universities continue to be a major "export earner" by attracting individuals from all over the world. Many of these people stay in America and contribute to American industry. While little can or should be done to restrict the return of those who want to go back to

their native lands, American immigration policy should allow those who can make a major contribution in this important field to stay here if they wish.

Adequate Protection for Intellectual Property. Improvement is clearly needed both in our own patent office, but particularly abroad. The Administration is committed to pursuing the protection of intellectual property in the current GATT negotiations in Uruguay as a top priority.

- o Improvements at the U.S. Patent Office Should Be Continued. The adequacy of personnel at the Patent Office has been questioned. Clearly, increased resources will be needed in the biotechnology field as the industry continues to grow.

- o International cooperation in patenting should be considered. It is difficult and expensive to obtain patents in every country. Efforts should be made to harmonize patent rules and testing requirements. Ideally, patents granted by one major country (the U.S. or Japan) should be accepted internationally.

Specific Challenge Facing Small Biotechnology Companies

Discriminatory Tax Rules. The Tax Reform Act of 1986 specifically "tilted the playing field" against small start up ventures. Biotechnology firms were particularly adversely affected by these changes. Some are being addressed by the Administration. Other changes should be considered.

- o Capital Gains. Jim Sherblom of Transgenic said that, A principal aid to the biotechnology industry, and small firms in particular, would be the passage of a capital gains tax rate reduction. Investors in start up biotechnology firms are high-risk investors who must tie up their funds for an extended period of time. He noted that his fellow entrepreneurs were all enthusiastic about the Administration's proposed capital gains tax rate reduction at their last meeting with investors. Large firms are less reliant on informal investors and on equity generally and therefore will tend to benefit less from a capital gains tax rate reduction.

- o Stock Options. Risk accrues not only to suppliers of capital, but also to entrepreneurs and managers. Compensation for this extra risk is important. Biotechnology firms use Stock Options as a form of compensation for many, if not most, of their employees. These options take on added value if the capital gains tax rate is reduced. This helps small biotechnology

companies attract talented personnel. Some changes now being considered in Congress would make these less attractive. Stock options are also used by small firms to attract people from larger firms. Therefore, larger firms tend to less than enthusiastic about this as a device.

- Asymmetric Treatment of Profits and Losses. Losses may be carried forward for up to 7 years. But, the average development time for a new biotechnology product is often longer than this. In addition, even if the firm becomes profitable before the end of the 7 year period, the time value of the tax loss is substantially reduced in the interim. This is much less of a problem for large, integrated firms who often have highly profitable divisions which can offset their losses in developing biotechnology products.

- Limits on the Research and Experimentation Credit. The credit, like losses, may be carried forward for only 7 years. The firm can only use this credit if it has tax liability. So, the credit can only become applicable if the firm is profitable after it has exhausted any existing loss carryforwards. Thus, many biotechnology firms lose their credits entirely. Others which may receive the credit receive it only at a sharply reduced present value. Again, large firms with profitable divisions can receive the benefit of the credit immediately.

- Transfers of Assets. These problems are exacerbated when a biotechnology firm is sold, or even goes to market with a new equity offering. The Tax Reform Act of 1986 limited the transferability of tax loss carry forwards if more than 50 percent of the equity in a firm changes hands. Thus, rapidly growing biotechnology firms might lose this tax advantage.

- Good Will. Biotechnology firms are also penalized by the contrasting IRS and FASB treatments of good will. Most of the value of a biotechnology firm is intangible -- the human capital of the employees. FASB rules require that this be depreciated, thus lowering the apparent earnings of the firm. IRS allow no deduction for this depreciation. Therefore, biotechnology firms face the twin problem of lower apparent earnings and higher taxes.

Public Policy and Industry Structure

Large integrated firms have inherent advantages at bringing new products to market. These include access to capital and expertise in manufacturing and marketing. On the other hand, a

good case can be made that small biotechnology firms have an inherent advantage at developing new products and new ideas. Their advantages include an increased effort by employees who feel part of a small team and who benefit greatly from their success as well as a less bureaucratic and more entrepreneurial company ethos. This leads to a number of observations.

1. Ideally, the market structure of the industry should include both small and large firms. Small firms can be the industry's inventors and innovators while larger firms will bring these inventions and innovations to market.

2. We should expect corporate buyouts in the industry. When a small firm has developed a product, it is natural for the firm to be acquired by a larger firm with expertise in manufacturing and marketing. A free market for corporate control is therefore probably beneficial to the competitiveness of the industry.

3. Public policy should not tilt in favor of either small firms or large firms. On the one hand, aggressive and myopic anti trust enforcement is totally inappropriate. It will be natural for monopolization to occur in narrowly defined market niches as the industry grows. Joint production and research ventures should be encouraged as a way of minimizing capital costs and risks.

   On the other hand, the current tax law bias against small firms may cause an overconcentration in the industry and an excessive reliance on large, diversified manufacturers. These larger firms may not place sufficient emphasis on their biotechnology divisions. We should consider tax law changes to help level the playing field between large and small firms in this area.

3/9/90

SCIENCE AND TECHNOLOGY TASK FORCE

OF THE WORKING GROUP ON BIOTECHNOLOGY

OF THE COUNCIL ON COMPETITIVENESS

A number of recommendations were made by the Task Force to strengthen the fundamental research that supports the new biotechnology as well as the more distal scale-up steps, all of which are depicted in Fig. I. Particular emphasis was directed to research and training needs that will be essential to support this field from discovery to marketplace. A key element in the plan is enhanced cooperation among academia, government and industry in multidisciplinary and multi-institution research and training, coupled with sufficient support to enable investigators and trainees to have adequate equipment required to be competitive in sustaining and enlarging our expertise in this field.

A. Molecular Biology and Cloning

Problem: Funding basic research on merit, the United States was the pioneer in the development of rDNA technology that fostered the new biotechnology. However, after a period during which NIH was funding approximately 40% of approved grants, the funding of approved grants for basic biomedical sciences decreased to approximately 24% in FY 90. One implication of this shortfall is that a substantial amount of pre-commercial research is going unfunded and unperformed in the United States. In meeting these needs, it is important that Federal Government funds are leveraged with appropriate monies from academe, industry, and state governments. Remedies for these problems would enable us to expend resources on the development of model systems for cloning of genes; expression of newly acquired genetic information; characterization and sequencing of DNA, RNA and proteins; genetic research on physiological processes such as post-translational secretion, intracellular transport mechanisms, and processing events; and biocomputation and information management systems to store and analyze large amounts of sequence information. Similar deficiencies in training programs and shortages of practicing scientists exist in biotechnology-related scientific fields, according to surveys by NSF and the Industrial Biotechnology Association [the former is shown in Appendix 1].

Solutions:

- Enhance the support of molecular genetics, molecular biology, physical chemistry, immunobiology, and information management. Particular emphasis should be directed towards the development of multidisciplinary research efforts, particularly the integration of the biological, engineering and physical sciences. Specifically, areas of emphasis should include: studies of model organisms used as hosts for expression of cloned gene products and mechanisms of their post-translational

modification, transport, and secretion; protein engineering; protein folding/chemistry, and analyses of three-dimensional structure; ligand-receptor interactions; biocomputation, informatics, and computer modeling of complex structures and processes, including intercellular communication.

- To ensure a sufficient supply of broadly educated trainees, the Government should enhance the training of scientists in the biomedical, bioengineering, and agricultural fields in an interdisciplinary fashion. As exemplified by the integration of molecular biology into many of the other scientific fields constituting "biotechnology," the boundaries are disappearing between the various fields in the biological sciences, and it is now time to integrate the engineering and physical chemistry disciplines with the biological sciences that are at the core of biotechnology. Existing USG responses to this need include NIH/NIGMS interdisciplinary predoctoral and postdoctoral research training programs in biotechnology and NSF interdisciplinary predoctoral programs. These should be expanded within NIH and NSF and instituted in other funding agencies (USDA, DoE). Moreover, additional multidisciplinary centers should be established in universities that combine these different fields and wherever possible, different institutions as well. These would build on the models of the existing NSF programs of engineering research centers and science and technology centers [Appendix 2]. Particular attention should be directed to the melding of the biological, physical, engineering and information management sectors.

- Improve quality of equipment in university laboratories -- state-of-the-art computers, bioreactors, computer-assisted separation systems, sequencers, polymerase chain reactor devices, and DNA synthesizers. This could be accomplished in part by the expansion of highly cost-effective shared equipment grants.

Problem: Specific gaps exist in our understanding of model systems that can be used generically to augment the knowledge base required for the first, pre-competitive stages of product development.

Solutions:

- Improved understanding of gene expression in a number of model systems likely to be used in scale-up is essential, and these systems should be a focus for increased resources. These should include (but not be limited to) *Escherichia coli*, *Saccharomyces cerevisiae*, *Bacillus subtilis*, *Agrobacterium tumifaciens*, *Rhizobium species*, RNA retroviruses, *Arabidopsis*, hybridomas and plant protoplasts, and established mammalian and Lepidopteran cell lines.

- Fundamental research on factors that affect the technical aspects of scale-up; e.g., factors affecting cellular growth and gene expression in liquid phase and solid/liquid phases of cell growth.

- Fundamental research in structural biology, including protein structure-function relationships; and analysis of metabolic pathways that influence expression of newly acquired genetic information.

B. Scale up from the Laboratory to the Marketplace

Problem: Insufficient research on large scale development, including protein engineering, separation sciences, stability/purification/recovery of proteins, bioprocess and biochemical engineering, and bioreactor design.

Solutions:

- Fundamental model system work on parameters that influence scale-up, such as cellular shear, regulation of gene expression, and mechanical requirements for growth. This would inspire innovative ways to produce cells in solid matrices or in aggregates, and general principles to optimize product secretion or crystallization. Much of the technology, particularly in human and animal cells, is more than 30 years old, cumbersome and inefficient; for example, roller bottles and spinner flasks are still used in the commercial-scale production of biotechnology products from cultured mammalian cells. It is important to undertake research on new methods for growing cells that can be applied to other systems. Progress in the development of superior bioreactor systems could enable rapid increases in cost-efficiency. This is especially important in the production of amino acids, enzymes, solvents and pharmaceuticals.

- Downstream purification is extremely important in obtaining high quality products from fermentation. Fundamental research that will complement that in the private sector may be required for improvements in the purification of proteins, glycoproteins and other macromolecules. Consideration should be given to developing new procedures in purification, such as the use of immunological reagents, absorption to complex matrices, and large-scale fractionation. Such research merges the physical, engineering and biological sciences.

- State-of-the-art instrumentation, including robotics, biosensors, and automated analytic, sequencing, and synthesis technologies is essential throughout the spectrum from laboratory to marketplace; it must be made available to investigators and updated periodically.

- Development of multidisciplinary training centers in biomechanical engineering in universities to catalyze interaction among the physical, engineering, and biomedical sciences. Particular emphasis should be given to the provision of adequate equipment that will enable both faculty and students to model research on the processes involved from laboratory scale to intermediate scale fermenters (500 liters) and where

appropriate, to larger scale fermenters. These large multidisciplinary training grants should, wherever possible, have joint funding from academia, government and industry to leverage governmental investment and to foster intermingling of personnel among the various sectors. Training should be encouraged beyond geographic and university boundaries.

C. Non-scientific factors influencing innovation in and commercialization of biotechnology

Problem: Incipient regulations on conflict of interest are on a potential collision course with the technology transfer policy of the USG. Because conflict of interest policy will involve university, industry and government scientists, it is imperative that it receive careful analysis by the working group.

Solution: The Federal Technology Transfer Act, enacted in 1986, encouraged closer interaction between government-supported and governmental scientific investigators and industry. While there has been a marked increase in the frequency of interaction between these scientists and industry, few problems have been identified. One issue of concern is developmental research that leads to commercial applications such as clinical trials for pharmaceuticals and devices and field testing for agrochemicals; this pre-commercial testing could emerge from joint ventures or collaborations. Because there is continuity of research between discovery and patent, it is recommended that disclosure be limited to situations in which patents are pending or have been issued such as pharmaceutical agents used in clinical trials. This would not effect the basic research phases of discovery and development.

Problem: Developments that could discourage the necessary use of animals in research.

Solution: Guidelines should be developed for the ethical use of animals that include substantial penalties for the disruption or destruction of laboratory facilities or research.

Problem: Critics of the Small Business Innovation Grant program have suggested that the Government's passive administration of this program may have led to substantial underutilization of its resources.

Solution: While examples of successful biotechnology SBIR grants shown in Appendix 3 indicate that this mechanism works, its efficiency should be evaluated to determine whether the funds can be utilized more effectively to bridge the gap between innovation and production in the field of biotechnology. This reutilization could be directed at some of the solutions enumerated in this document.

D. Federal Technology Management

Problem: The Federal Technology Transfer Act (FTTA) mandated the facilitation of technology transfers between federal laboratories and the private sector. This was intended to enhance the return to taxpayers from the investment in federal research programs. Concerns have been expressed about the level of use and effectiveness of the new programs developed under the Act.

Solution: Implementation of the FTTA should be reviewed and coordinated to enhance the efficiency of information exchange and technology transfer.

APPENDIX I

Table A-1. Occupational Employment in Dedicated Biotechnology Companies, 1989

Occupation	Total Employed	Total Employed Ph.D.s	Shortage as % of Employed	Planned Hires as % of Employed
BIOTECHNOLOGY SPECIALTIES				
Molecular Genetics	724	340	2.7%	13.8%
Classical Genetics	42	20	5.1%	15.3%
Industrial Microbiology	311	72	9.8%	29.3%
General Microbiology	665	248	1.2%	10.1%
Human/Animal Cell Biology	471	198	3.0%	10.1%
Plant Cell Biology	86	45	4.5%	13.4%
Human/Animal Molecular Biology	508	309	9.7%	21.7%
Plant Molecular Biology	90	55	3.7%	11.0%
Human/Animal Biology	246	87	3.4%	11.5%
Plant Biology	42	25	4.0%	15.8%
Pharmacology	209	93	11.9%	25.9%
Toxicology	73	17	17.8%	29.7%
Enzymology	81	59	11.9%	27.2%
Immunology	532	216	7.9%	20.8%
other biology	154	39	2.5%	15.3%
Analytical Biochemistry	377	156	3.9%	20.5%
General Biochemistry	1042	498	6.0%	17.7%
Other Chemistry	1397	644	5.0%	21.7%
Other Biotechnology Specialties	369	163	3.7%	43.0%
TOTAL	7420	3282	5.4%	19.4%
OTHER SCIENTISTS				
Medical Science, MD	66	0	0.0%	0.0%
Medical Science, non MD	104	18	0.0%	65.8%
Health Physics	3	0	0.0%	0.0%
Agricultural Sciences	73	27	3.8%	3.8%
Other Physical Sciences	191	43	11.5%	16.1%
Behavioral/Social Sciences	310	67	3.0%	3.0%
Computer Sciences	655	59	1.7%	1.7%
Mathematics	115	31	22.7%	16.2%
TOTAL	1517	246	6.5%	11.4%
TOTAL SCIENTISTS	8937	3527	5.5%	18.8%
ENGINEERS				
Biochemical Engineer	170	0	9.1%	30.6%
Bioengineer	279	0	14.6%	25.6%
Bioprocess Engineer	115	0	3.7%	50.0%
Other Engineers	2337	0	2.0%	12.4%
TOTAL ENGINEERS	2901	0	3.7%	16.4%
TOTAL TECHNICIANS	5597	0	3.6%	19.4%
OTHER EMPLOYMENT	36550			
TOTAL EMPLOYMENT	53985			

NOTE: Shortages and new hires for engineers and technicians are computed on total employment; for scientists the base is Ph.D. employment. Shortages are defined as unfilled vacancies for 90 days or longer.

SOURCE: NSF Survey of Dedicated Biotechnology Companies, 1989.

APPENDIX II

- Industry University Cooperative Research Centers
  - University of Maryland-life cycle engineering
  - University of North Carolina/Duke University-monoclonal lymphocyte technology
  - University of Texas Health Sciences Center-cell regulation;
- Biological Research Center
  - Johns Hopkins University-biophysical studies on macromolecular assemblies;
- Plant Science Center
  - Cornell University-experimental analysis and transfer of plant genes.
- Science and Technology Centers
  - California Institute of Technology-Center for Development of an Integrated Protein and Nucleic Acid Biotechnology-a collaboration between the Caltech and industry for the development of the most advanced techniques for genetic engineering, protein engineering, protein chemistry, and data analysis in order to speed research in protein and gene regulation.
  - Michigan State University-Center for Microbial Ecology-a university-industry research program devoted to understanding of microorganisms and their function in their natural and man-made habitats by focusing on gene pool accessibility, population diversity, community diversity, novel organisms, physicochemical environment as related to improvement in groundwater quality, hazardous waste disposal, plant pest control, recycling of nutrients, fermentation, and other industrial processes, the development of safe genetically engineered organisms.
- Engineering Research Centers
  - Duke University and other North Carolina institutions and industries-Center for Emerging Cardiovascular

Technologies-a university, biotechnology, industry, state of North Carolina, and NSF and NIH funded Center devoted to creation of the knowledge needed to design and produce a new generation of advanced biomedical systems, devices, and instruments for cardiac intervention systems and cardiovascular imaging systems,

- Massachusetts Institute of Technology and biotechnology industries-Biotechnology Process Engineering Center-a Center focusing on integrating the life sciences and bioprocess engineering with the goal of producing advanced manufacturing technologies. Research thrusts are:

  (a) genetics, molecular biology, and biochemical principles in protein production;
  (b) engineering principles in protein production;
  (c) downstream processing in biotechnology.

- Montana State University-Center for Interfacial Microbial Process Engineering-a collaboration between the university, relevant industry, and the Department of Energy's Idaho National Engineering Laboratory addressing microbial phenomena related to degradation of hazardous substances and microbial processes in fouling and corrosion.

For these centers organized to address complex problems requiring scale, duration, facilities , and collaborative relationships that best accommodate the overall research objectives, there is, nonetheless, an explicit education and human resource development component.

APPENDIX III

Representative Cooperative Research and Development Agreements (CRADAs) of NIH

- A successful collaboration between NIH intramural scientists and Integrated Genetics, Inc. resulted in the first report of the production of a biologically active human therapeutic protein in the milk of laboratory mice.

- An American Pharmaceutical company is collaborating with National Cancer Institute investigators on studies to produce large amounts of recombinant uromodulin, an immunosuppressive protein shown to have a role in regulating the circulating levels of biological response modifiers (interleukin-1, tumor necrosis factor), via recombinant DNA technology, for subsequent evaluation of its clinical usefulness.

- Several pharmaceutical companies and NIH scientists are collaborating in studies of the autocrine motility factor, a protein produced by certain cancer cells and found to play an important role in the process by which cancer cells invade distant sites in the body, with the goal of identifying therapeutic agents that inhibit this motility factor; thereby facilitating the localization of metastases and allowing predictions of the aggressiveness of a particular cancer in an individual patient.

- NIH investigators and those of several biotechnology companies are focusing on the production of immunotoxins (i.e., a monoclonal antibody attached to a toxin) for: (a) preliminary treatment of adult T-cell leukemia; (b) inhibition of ovarian cancer cells; and (c) the construction of modified immunotoxins with increased effectiveness in cancer treatment.

- In another NIH-industry collaboration, biotechnological studies have resulted in the identification of the gene encoding for the membrane protein responsible for the selective transport of drug often used in cancer chemotherapy. It is now possible to develop molecular (DNA) probes that will detect the presence of this gene and thereby allow the development of a new generation of chemotherapeutic agents (drugs) that are not affected by the membrane transport protein, thus leading to the absence of drug resistance.

- NIH scientists cooperating with researchers at Genentech

have produced large quantities of osteogenic, a protein bone growth factor presumed to be important in effective regeneration of bony tissues of the head and face, for much needed medical applications.

- o In a landmark achievement in hematologic research, NIH-sponsored scientists collaborated with AMGEN, to clone the gene for erythropoietin, the major hormonal regulator of red blood cell production. Currently, large scale production of the commercially available biotechnology product had made provisions for effective treatment of chronic anemia.

- o NIH scientists played major roles in developing of an experimental HIV vaccine, which is being developed by a biotechnology firm.

DRAFT

REPORT ON

REGULATORY ISSUES

Regulatory Task Force

Working Group on Biotechnology

Background

Where private markets fail to provide adequate incentives to avoid unreasonable risks, appropriate levels of regulation can protect public health and environmental welfare, enhancing safety and increasing public confidence in these new technologies. In these circumstances, regulation can shield the industry from avoidable incidents that could tarnish its image and impair its development. In 1986, a coordinated Federal effort set out the groundwork for achieving the delicate balance between encouraging innovation in biotechnology while protecting public health and the environment from unreasonable risk.[1]

The Coordinated Framework established a roadmap for Federal regulation of biotechnology, and incorporated the principle that

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[1] "Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment," 51 FR 23302.

regulation should focus on the characteristics and risks of an organism, not the process used to produce it. Based on the principles outlined in the Coordinated Framework, the Food and Drug Administration (FDA) announced that it did not need to establish any new procedures for genetically-engineered products. FDA's review of products is based on case-by-case review of risks and use. However, the other two major regulatory agencies -- the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA) -- announced that they would need to develop additional rules. USDA proposed to develop new rules in some areas for reviewing genetically-engineered organisms and products that could pose high risks (e.g., plant pests, viruses, etc.). EPA also proposed to develop new regulations for the review of microorganisms that are likely to pose risks. Figure I illustrates the intervention points for likely Federal regulatory review in the course of research and development of biotech products.

Regulatory Barriers to Innovation in Biotechnology

In serving as "gatekeepers" for the development and use of new biotechnology products, however, regulatory agencies may create substantial regulatory uncertainty associated with both the potential for delay in regulatory approval and the possible imposition of extensive restrictions or outright disapproval of new biotech products. Both delay and regulatory uncertainty can serve to discourage new research in regulated areas as well as curtail the development of new products. Industry

representatives reported to the Task Force, for example, that corporate strategies are increasingly based on avoiding rDNA approaches because of both the direct regulatory costs and the uncertainty associated with regulatory review of products using these techniques.[2] These indirect "costs" of regulatory agency review can substantially outweigh the direct costs associated with the testing and paperwork requirements for regulatory agency approval and the regulatory restrictions placed on development, manufacture, and use of products.

The effects of regulatory delay can be particularly devastating to small firms because, as relatively high-risk investments, they face very high costs for obtaining capital investment. But even larger, well-established corporations require substantially larger expected future profits to pursue research in areas where there are burdensome regulatory requirements and the criteria for review are open-ended. As a result, the level of regulatory review necessary to consider properly the potential risks must be carefully constructed and monitored to avoid excessive

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[2]Dr. Nanette Newell, Synertech. There are similar reports in the press; for example, a Vice President of Biotechnica International Inc., reported that because of regulatory delay in approval of field testing "...the company has turned away from experimenting with altered genes and is working instead with less stringently regulated mutant genes, thus, sacrificing scientific accuracy to reduce bureaucratic delay." Wall Street Journal, January 30, 1989.

restrictions that curtail the benefits to society of biotechnology.

Principles of Regulatory Review

1. Federal government regulatory oversight should focus on the characteristics and risks of the biotech product -- not the process by which it is created.

   -- Where biotech products pose little or no risk, appropriate exemptions from regulatory review should be made for both testing and commercialization. A focus on specific products (or classes of products) that may pose risks concentrates regulatory oversight on areas of concern and leaves relatively unfettered those biotechnology products posing little or no risk.

2. Where products require review, regulatory review should be designed to minimize regulatory delay while assuring protection of public health and welfare. Lengthy and cumbersome review procedures can result in an impenetrable regulatory process that stifles innovation.

   -- Where possible, expedited review procedures should be adopted for products likely to pose lesser risk. Tailoring the review process to the level of risk posed by the product assures protection of public health and the environment while minimizing regulatory delay.

-- The jurisdiction of the several regulatory agencies should be clarified to avoid unnecessary confusion and delay.

3. Regulatory programs should be designed to accommodate the rapid advances in biotechnology.

-- Regulatory procedures should provide flexibility to accommodate a rapidly changing science base in biotechnology. Performance-based standards are generally preferred over design standards. A performance standard sets the ends or goals to be achieved, rather than specifying the means to achieve it (e.g., through a design standard). This provides firms with flexibility in choosing the best means of compliance.[3]

-- In addition, properly defined performance criteria can more readily adapt to advances in the science and accommodate changes in regulatory scope with the accumulation of experience in biotechnology. The adoption of performance criteria in the regulatory process reduces the need to rely on a lengthy and contentious regulatory process to revise regulations.

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[3]A performance-based standard for containment, for example, would provide a far more flexible approach that would allow biological approaches for assuring containment in place of a design-based standard requiring, for instance, specific physical barriers.

Such unwieldy regulatory processes inevitably inhibit the changes in regulatory structure needed to accommodate advances in the science base.

4. Regulation in other areas should rely on performance goals or standards, rather than mandating rigid controls or specific designs for compliance. Performance standards create opportunities for innovative solutions which could involve new biotechnology products.

   -- Performance standards in other (traditional) regulatory programs would reduce the barriers to biotechnology products in competing with traditional technologies. For example, current statutory criteria and regulatory requirements for the disposal of hazardous waste that are based on the use of incineration discourage the development and use of other techniques. These "design-based" criteria and requirements may preclude bioremediation techniques even though the biotech application may be both less costly and more effective.

Initiatives to Reduce Regulatory Barriers to Biotechnology

1. Improve interagency coordination to reduce regulatory delays and jurisdictional uncertainties.

2. Review FDA drug approval process: improve design of small scale human trials (Phase II) and eliminate large scale

trials (Phase III), where possible. [Scale-up]

3. Develop a risk-based approach for field tests; implement this approach in ABRAC guidelines and the proposed rule for FIFRA. [Scale-up]

4. Revise the NIH guidelines to reflect current perspectives that regulation should focus on the characteristics and risks of the product, rather than on the process used. [Scale-up]

5. ~~Examine~~ Establish sunset or other mechanisms to provide the regulatory flexibility needed to respond to rapid advances in the science base.

6. Improving Intellectual Property Rights

The uncertainties in intellectual property rights for innovations in the biotechnology area continue to hamper the industry. Two changes in U.S. law have been suggested as a way of improving patent protection.

-- Determine the appropriate way to correct a recent PTO interpretation of a court case (In re Durden) that suggests use of a novel starting material in combination with a known chemical process is not eligible for a process patent. The application of Durden in the biotechnology area could deny protection to innovations

that can only be protected through process patents.

-- Amend the Tariff Act of 1930 to provide the International Trade Commission with jurisdiction to exclude imported products produced by using biotechnological materials covered by a U.S. patent.

In addition, improvement of patent laws in other countries would provide U.S. biotechnology firms with better protection from patent infringement by foreign companies. Some of these issues are already under discussion in current GATT negotiations (Uruguay round).

Finally, backlogs in approval of patent applications can discourage both investment in biotechnology research and the development of new products. To address this problem, the Administration's 1991 budget includes hiring 100 new patent examiners over the next five years and improving training for examiners. In addition, the Patent Office is setting up an information system that will establish a comprehensive data base of patent information, substantially facilitating the review of patent applications.

7. Address problems with State and local laws.

Some States and local governments have adopted regulatory requirements (and even the prohibition of biotech activities) that are specifically directed to biotechnology research and

development. These are typically process-based regulations. Some have suggested that if other States adopt similar legislation, or more importantly, place limits on the commercial use of biotechnology products, there may be a need for Federal intervention. Under current law, USDA and EPA do not have the authority to preempt State law.

THE WHITE HOUSE

WASHINGTON

March 5, 1990

MEMORANDUM FOR OLIN WETHINGTON
KEN YALE

FROM: STEPHEN I. DANZANSKY

SUBJECT: Science and Technology Working Groups

In light of David and my conversations with Allan Bromley and Larry Lindsey on the subject of S&T Turf, the following assignments should be pursued:

- Bromley would like our comments and changes to the FCCSET charter and working documents communicated by memorandum to his office by Friday, March 9. He has agreed to accept almost all of these, but insists upon his right to call together the heads of departments to FCCSET organizational and status reporting meetings in order to keep high-level attention on the coordinating role of FCCSET. He has agreed to accept the chairmanship of the DPC and EPC S&T Working Groups as the policy channels through which the relevant councils would percolate decisions to the President.

- Both of you will need to review the FCCSET documents, get White House Counsel legal guidance, and prepare a memo to Bromley for David's signature into our Staff Ops system by Friday morning.

- The next step will be to get the EPC and DPC charters drafted or redrafted to take into consideration the following:

  a. complimentary jurisdictions of EPC and DPC over S&T issues; each Council's charter must reflect the separation of domestic and economic issues.

  b. the EPC charter as redrafted should except from consideration those issues which the Competitiveness Council will take up. Since the President's speech called for the CC working group to "find ways that American industry can better translate new ideas and technologies into marketable products," Olin will need to meet with Larry Lindsey to work out what that means in terms of issues and jurisdiction and redraft the EPC charter accordingly.

- The new charters would be submitted through Staff OPS to the Chairmen Pro Temp. Once signed, an announcement could be made of the new Bromley chairmanships.

We would like to see this whole business completed by the end of next week so that the Cabinet can be notified. I'm happy to consult and counsel with you on any of this if you run into problems.

Thanks for following up.

cc: David Q. Bates

THE WHITE HOUSE

WASHINGTON

March 12, 1990

MEMORANDUM FOR TOM RACHFORD

FROM: STEPHEN I. DANZANSKY
Deputy Assistant to the President and
Director of Cabinet Affairs

SUBJECT: FCCSET CHARTER

Thank you for giving us the opportunity to review and comment on the charter of your Federal Coordinating Council on Science, Engineering and Technology (FCCSET).

Forgive our perpetual lateness on these matters, but as between our two policy Councils, the Competitiveness Council, White House Counsel's Office, and a few last minute cross checks and double takes, it literally could not be turned around sooner. My staff will attest to the fact that I was in the office all weekend, in part to resolve this S&T business.

Enclosed is our mark-up of your FCCSET charter, altered to reflect its original statutory mission. Such a pruning, in our opinion, will answer both the legal and cross-policy questions raised with you and Allan in David's office last week.

Substituted therefore is a draft charter for a joint EPC/DPC Working Group on Science and Technology which we would want Allan to chair, and under which several task forces could be formed to focus upon micro-policy questions (e.g., tax incentives for research and experimentation). I see this Working Group meeting at Cabinet or subcabinet level.

What this reconfiguration does, I believe, is place Allan in the middle of the switchboard of S&T policy much as Bill Bennett is at the center of drug policy: the S&T Czar. Working with us, Allan can decide which policy issues go where and also keep control of the agenda insofar as the Competitiveness Council wishes to target on specific S&T issues like biotechnology.

We have to do more talking about the composite picture, but I believe that this configuration will serve both of our objectives well; and most important, those of the President.

Thanks for working with us and for your patience.

cc: David Bates

THE WHITE HOUSE

WASHINGTON

February 3, 1990

MEMORANDUM FOR DAVID Q. BATES

FROM: KENNETH P. YALE KY

SUBJECT: Federal Coordinating Council on Science, Engineering and Technology (FCCSET)

BOTTOM LINE: The Office of Science and Technology Policy is revitalizing their FCCSET organization. Unless we have full coordination with OSTP staff, FCCSET could duplicate existing processes in the Cabinet Councils and create confusion.

BACKGROUND: A FCCSET meeting was held on January 24, 1990 to discuss: 1) the structure and function of FCCSET, 2) the structure of FCCSET Committees, and 3) financing and support personnel for FCCSET (see attached briefing book).

An elaborate FCCSET structure was envisioned, basically a scientific Cabinet Council, chaired by Dr. Bromley. It would have interagency committees with representatives at the assistant secretary level or above. Although there was some mention of taking issues to the appropriate Cabinet Councils for review, it was also stated that the FCCSET would resolve science and technology policy issues.

Unless there is very close coordination with DPC and EPC, FCCSET could encourage forum shopping and circumvent the DPC and EPC processes. Instead of career level scientists preparing background reports on science issues and acting as a clearinghouse for information (eg., the CES), it appears the proposed FCCSET formulation could consist of political level people (ie. Assistant Secretary) developing policy -- a very different function. You will recall that the original DPC and EPC charters stated they would formulate, coordinate and implement policy and "serve as the primary channels for advising the President on policy."

RECOMMENDATION: We should be actively involved in the development and operations of FCCEST, to avoid forum shopping and confusing signals to the agencies. The value of FCCSET committees composed of knowledgeable, career level scientists -- developing reports and acting as information clearinghouses for agencies and DPC/EPC working groups -- should be emphasized. Regular meetings between OSTP Associate Directors and Cabinet Council Executive Secretaries would be appropriate.

THE WHITE HOUSE

WASHINGTON

February 5, 1990

MEMORANDUM FOR D. ALLAN BROMLEY

FROM: DAVID Q. BATES

SUBJECT: Federal Coordinating Council on Science, Engineering and Technology

Thank you for including us in the development of your Federal Coordinating Council on Science, Engineering and Technology (FCCSET). I am responding to the request for comments on the FCCSET structure. You may contact Ken Yale for more specific comments and recommendations.

We would like to work closely with you as your FCCSET committees get up and running. The scientific expertise which your Committee on Earth Sciences brings to the DPC Global Change Working Group has been very beneficial. There is much value in assembling scientific staff from the agencies to investigate the underpinnings of the issues faced by the Administration.

My staff and I look forward to working with you as your FCCSET Committees develop. Our Cabinet Councils and associated working groups are at your service. You may find them a valuable resource as the FCCSET Committees develop reports and background papers.

As the "primary channels to advise the President on policy" -- and without agency, statutory or advisory status -- both the DPC and EPC are fully protected by executive privilege. As a result, they are not subject to many of the statutory restrictions that make it difficult for political appointees to have a full and frank discussion. Thus, you may want to consider close coordination with the DPC and EPC in order to develop a process for full and adequate vetting of issues that are Presidential in nature or require Presidential or Cabinet attention or decisions.

Again, I thank you for allowing us to participate. Should you have any questions, do feel free to contact myself, or the Executive Secretaries of the Councils: Lehmann Li and Ken Yale.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

February 12, 1990

Dear David:

As you know, on January 24 I chaired the first meeting of the Federal Coordinating Council for Science, Engineering and Technology. I was pleased to have Ken Yale from your staff there to represent the Office of Cabinet Affairs. I believe that we are off to a good start on putting together a clearly much-needed structure to address and coordinate cross-cutting science and technology issues within the Administration. I would like to take this opportunity to fill you in on the outcome of our meeting and to extend a personal invitation to you to participate in succeeding meetings. I would greatly appreciate your support and input in these initial months as we develop the charter, committee structure, and staffing arrangements.

Several issues were raised during the course of our discussion on the 24th, some of which are fairly easy to resolve while others will require the careful consideration of all FCCSET members. First, I think there was a general consensus that we need to define in more detail the functions and activities of the FCCSET. There were concerns expressed, for example, about the FCCSET's role vis-a-vis the President's Council of Advisors on Science and Technology (PCAST), the types of issues the FCCSET would address, FCCSET's role in the budget process, possible duplication of the functions of other policy coordinating bodies such as the Domestic Policy Council and the Economic Policy Council, frequency of meetings, etc.

In general terms, we have agreed that the future success of FCCSET and of its committees depends crucially upon the participation of very senior policy level representatives of the member agencies both in the FCCSET and in its committees.

We have also agreed that inasmuch as I chair both FCCSET and PCAST, I shall accept the responsibility for insuring communication between the private sector PCAST panels and the FCCSET committees and working groups that may be established to consider parallel issues.

You will find attached a draft charter for the FCCSET which I believe addresses these and other issues concerning the role, structure and functions of the FCCSET. I request that you give this draft careful consideration and let me know your thoughts on how it might be modified or improved.

Second, at our meeting on the 24th, we discussed possible changes in the list of FCCSET committees. There was general consensus that we should keep the number of committees down but no agreement on how to accomplish that objective. There are, I think you would agree, two types of committees. First, there are those that are designed to oversee functional areas of R&D, such as health and life sciences or mathematical and physical sciences. These committees would be responsible for coordinating cross-cutting activities within their field of responsibility and reporting on emerging issues and policy concerns. (I have attached a draft sample charter for this type of committee.)

There are also those committees that are designed to address cross-cutting concerns that affect the scientific well-being of this country but go beyond the confines of any one functional area. They have a policy focus or enabling character that cuts across all of the functional areas. Examples are: education, industrial technology, and international science and technology.

Each of these two types of committees has validity within the FCCSET structure and I would suggest that we find a way to keep both when needed. I have attached a revised committee structure which incorporates many of the suggestions from our meeting. In addition, I have suggested some cross-cutting issues that may be included in the mandate of these committees. I encourage you to review this suggested structure in detail and let me know whether or not it meets the needs of your agency.

I am also interested in your ideas on critical cross-cutting issues which require FCCSET attention and your suggestions as to which committee they might be assigned. I encourage you to be as creative as possible and not necessarily restrained by the committee structure suggested, because, it is by the development of a variety of cross-cutting issues, that we will be able to test the validity of the suggested framework.

A third issue coming out of our meeting on the 24th was the need for a FCCSET executive secretariat. I am in the process of developing a list of candidates to serve in this capacity. I am inclined to identify one senior, and one mid-level professional staff person, together with support staff, to serve in the executive secretariat to the FCCSET. The executive secretariat would be responsible for coordinating our activities as well as overseeing the FCCSET committee structure. I would be interested in any thoughts you have on this structure as well as any candidates you believe merit consideration. One of the first tasks I will assign the executive

secretariat is to work with the Department of Education to develop the necessary language to amend PL 94-282 to incorporate the Department of Education as a permanent member of the FCCSET.

I am anxious to move rapidly on all of these issues. As you know, there are a number of urgent concerns that require FCCSET attention, and I would like us to get to work on these posthaste. Therefore, I have asked my staff to try to arrange the next meeting of the FCCSET as soon as possible. They will be contacting your office to find a mutually convenient time. I hope that during the course of the meeting we can reach agreement on the charter and the committee structure. I want to try and have the executive secretariat established by that time. Therefore, if you have candidates in mind for these positions, please let me know by February 14 so that I can give them fair consideration.

Again, let me thank you for your continued support, and I look forward to seeing you at our next meeting.

Sincerely yours,

Allan

D. Allan Bromley
Director

Attachments:

Tab A	Draft FCCSET Charter
Tab B	Suggested Committee Structure
Tab C	Sample FCCSET Committee Charter
Tab D	FCCSET Membership List
Tab E	Attendees at January 24 FCCSET Meeting

The Honorable David Q. Bates, Jr.
Assistant to the President
and Secretary to the Cabinet
The White House
Washington, D.C. 20500

cc: Kenneth P. Yale

February 6, 1990

DRAFT CHARTER

Federal Coordinating Council For Science, Engineering and Technology

LEGISLATIVE MANDATE

The Federal Coordinating Council for Science Engineering and Technology (FCCSET) was established in 1976 pursuant to Public Law 94-282, Title V of the "National Science and Technology Policy Organization and Priorities Act of 1976" to consider cross-cutting science, engineering and technology issues. the law states that:

> "The Council shall consider problems and developments in the fields of science, engineering, and technology and related activities affecting more than one Federal agency, and shall recommend policies and other measures designed to:
>
> (1) provide more effective planning and administration of Federal scientific, engineering, and technological programs,
>
> (2) identify research needs including areas requiring additional emphasis,
>
> (3) achieve more effective utilization of the scientific, engineering, and technological resources and facilities of Federal agencies, including the elimination of unwarranted duplication, and
>
> (4) further international cooperation in science, engineering, and technology."

OBJECTIVES

In fulfilling this mandate, the FCCSET's two major objectives are:

- to provide authoritative scientific and technological expertise and advice to policy discussions and decisions to other cabinet-level councils including the National Security Council, the Economic Policy Council, the Domestic Policy Council, the Space Council and the Competitiveness Council.

- to coordinate science and technology efforts affecting more than one Federal agency and surface and resolve S&T policy issues.

FUNCTIONS

To accomplish these two objectives the FCCSET will:

- serve as a central coordinating forum for addressing problems and issues affecting more than one Federal agency, sharing information, reviewing national and international policy objectives and developing consensus;

- identify priority research and development needs;

- facilitate continuing cooperation in planning coordination and communication among Federal agencies on science and technology issues;

- issue reports, studies and assessments of current S&T capabilities in fields of research and development of concern to the Administration;

- provide reviews, analyses, advice and recommendations on science and technology matters to other policy coordinating bodies within the White House including the National Security Council, the Economic Policy Council, the Domestic Policy Council, the Space Council, and the Competitiveness Council;

- seek to inform other policy making bodies of reviews, studies and analyses underway, and coordinate activities so as not to duplicate functions with these bodies;

- identify science and technology issues and concerns of importance to the nation and bring policy recommendations to the attention of the President through appropriate policy bodies;

- with the close cooperation of the Office of Management and Budget, develop, and review annual and long-range Federal budget plans in selected cross-cutting areas of science and technology;

- improve planning, coordination and communication among Federal agencies engaged in science and technology.

ADMINISTRATIVE PROVISIONS

To accomplish these functions the FCCSET is authorized to:

- o detail employees to the Council to perform such functions, consistent with the purposes of the FCCSET, as the Chairman may assign to them;
- o establish committees for the purposes of conducting studies, making reports, coordinating Federal science and technology activities that involve more than one Federal agency, and making recommendations to the FCCSET;
- o develop, and review on an annual basis, charters for committees, and assign high priority agenda items as necessary;
- o Council meetings shall be called by the Chairman as deemed appropriate and each agency member shall attend at a senior policy level;
- o Council proceedings, studies, and reports, either preliminary or final, shall be printed and distributed only with the Chairman's authorization.

MEMBERSHIP

The Council shall be chaired by of the Director of the Office of Science and Technology Policy and shall be composed of one policy level representative of each of the following Federal Agencies:

Department of Agriculture
Department of Commerce
Department of Defense
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior
Department of State
Department of Transportation
Department of Veteran's Administration
National Aeronautics and Space Administration
National Science Foundation
Environmental Protection Agency

Other Agencies may be requested to participate in meetings of the Council concerned with matters of substantial interest to such agency.

Treasury, Education

DETERMINATION

I hereby approve and adopt this Charter which is determined to be consistent with PL 94-282 which establishes the FCCSET.

Approved:

_____ _____

D. Allan Bromley
Chairman, Federal Coordinating
Council for Science, Engineering
and Technology

Date

FEDERAL COORDINATING COUNCIL
FOR SCIENCE, ENGINEERING AND TECHNOLOGY

SUGGESTED COMMITTEE STRUCTURE
WITH CROSS-CUTTING/SUBSIDIARY ISSUES

Committees:

Health and Life Sciences

Physical, Mathematical and Engineering Sciences

Earth and Environmental Sciences

Food Agriculture and Forestry Research*

Education and Human Resources

Technology and Industry

~~**International Science, Engineering and Technology**~~

Sample Cross-cutting/Subsidiary Issues:

Bioethics
Biotechnology
Global Change
High Performance Computing
Human Genome Research
Intellectual Property Rights
Manufacturing
Materials
Math and Science Education
S&T Initatives in Eastern Europe
S&T Information Collection, Utilization and Dissemination
Social and Behavioral Sciences
Technology Transfer

*Established by PL 94-282; legislative relief required if abolished or merged

February 6, 1990

DRAFT
SAMPLE FCCSET COMMITTEE CHARTER

The Committee on _____ is hereby established by action of the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET). FCCSET derives its authority from PL 94-282.

Purpose

The purpose of the Committee on _____ is to increase the overall effectiveness and productivity of Federal R&D efforts in [fields related to the committee's jurisdiction]. The Committee will address significant national policy matters which cut across agency boundaries and shall provide a formal mechanism for interagency science policy coordination and exchanges of information regarding the scientific aspects of [field of jurisdiction].

Functions

The Committee on _____ will:

- review national and international Federal R&D programs, including budgets, in [the field of committee jurisdiction];
- facilitate planning, coordination, and communication among Federal agencies engaged in [the field of committee jurisdiction];
- identify and define Federal R&D needs in [the field of committee jurisdiction];
- develop and update long-range plans, including funding levels, for overall Federal R&D efforts in [the field of committee jurisdiction];
- address specific programmatic and operational issues and problems which affect two or more Federal agencies;
- provide reviews, analyses, advice, and recommendations to the FCCSET on Federal policies and programs concerned with [the field of committee jurisdiction].

Structure

The Chairman of the Committee on _____ is appointed by the Chairman of the FCCSET.

Responsibilities of the Chairman:

- hold regular meetings of the Committee (no fewer than six per year) and approve agendas;
- submit an annual report to the Chairman of the FCCSET for review by the full Council;
- approve the establishment, continuation or termination of subcommittees, task forces and working groups as necessary to achieve the Committee's purpose;
- meet regularly (bimonthly) with the Chairman of the FCCSET and other Committee chairmen to evaluate progress, discuss policy coordination, receive new instructions from the FCCSET and report on ongoing activities.

The following departments and agencies are represented on this Committee at the Assistant Secretary level or above:

[All FCCSET members and any other agency or department not on the FCCSET but with S&T activities in the committee's field of jurisdiction].

Membership on subcommittees, task forces, and working groups is not restricted to Committee members and is established as the Committee Chairman may determine appropriate.

Committee activities will be coordinated by an Executive Secretary, designated by the Committee Chairman. Additional staff and funding assistance, consistent with the functions of this charter, will be provided by member agencies as required by the Committee chairman.

Private Sector Interface

The Committee will recommend to the Chairman of the FCCSET the nature of private sector advice needed to accomplish its mission. The Chairman of the FCCSET will take necessary steps to ensure appropriate interaction between the President's Council of Advisors on Science and Technology (PCAST) and the Committee. The Committee may also seek ad hoc advice from various private sector groups as consistent with the Federal Advisory Act.

Compensation

All members are full-time Federal employees who are allowed reimbursement for travel expenses by their agencies plus per diem or subsistence while away from their duty stations and in accordance with standard government travel regulations.

Documentation

Agendas and records of actions of Committee meetings are prepared and disseminated to members by the Executive Secretary. Records of actions are submitted to members for approval. Complete records of all Committee activities, including those of task forces and working groups, are maintained in the office of the Chairman. The Committee prepares a report for the Chairman of the FCCSET not later than 60 days after the end of each fiscal year. The report contains, as a minimum, the Committee's functions; a list of members; a list of subcommittees, task forces and working groups and their charters; the dates, places and agendas for all meetings; and a summary of the Committee's activities and recommendations during the year.

Termination Date

Unless renewed by the Chairman of FCCSET prior to its expiration, the Committee on _____ shall terminate not later than March 31, 1991.

Determination

I hereby determine that the formation of the Committee on _____ is in the public interest in connection with the performance of duties imposed on the Executive Branch by law and that such duties can best be performed through the advice and counsel of such a group.

Approved:

_____ _____

Chairman, FCCSET Date

MEMBERSHIP LIST
FEDERAL COORDINATING COUNCIL
FOR SCIENCE, ENGINEERING AND TECHNOLOGY

Chairman

The Honorable D. Allan Bromley
Assistant to the President
for Science and Technology
and Director
Office of Science and Technology Policy
358 Old Executive Office Building
Washington, D.C. 20506

Members

The Honorable Manuel Lujan, Jr.
Secretary of the Interior
18th and C Streets, N.W.
Washington, D.C. 20240

The Honorable Clayton Yeutter
Secretary of Agriculture
12th Street and Jefferson Drive, S.W.
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The Honorable Louis W. Sullivan
Secretary of Health and Human Services
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The Honorable Jack Kemp
Secretary of Housing and Urban Development
451 7th Street, S.W.
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The Honorable James D. Watkins
Secretary of Energy
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Washington, D.C. 20585

The Honorable Donald J. Atwood, Jr.
Deputy Secretary of Defense
The Pentagon
Washington, D.C. 20301

The Honorable William K. Reilly
Administrator
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

The Honorable Richard H. Truly
Administrator
National Aeronautics and Space Administration
400 Maryland Avenue, S.W.
Washington, D.C. 20546

The Honorable Erich Bloch
Director
National Science Foundation
1800 G Street, N.W.
Washington, D.C. 20550

The Honorable Thomas J. Murrin
Deputy Secretary
Department of Commerce
14th and Constitution Avenue, N.W.
Washington, D.C. 20230

The Honorable Elaine Chao
Deputy Secretary
Department of Transportation
400 7th Street, S.W.
Washington, D.C. 20590

The Honorable Anthony J. Principi
Deputy Secretary
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

The Honorable Richard T. McCormack
Under Secretary for Economic Affairs
Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Non-statutory Members

The Honorable Elizabeth Dole
Secretary of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

The Honorable Lauro F. Cavazos
Secretary of Education
400 Maryland Avenue, S.W.
Washington, D.C. 20202

Attendees
FCCSET Meeting
Wednesday, January 24, 1990

Agency	Principal	Staff
HHS	Louis W. Sullivan	Dr. William E. Bennett Special Assistant to Secretary Sullivan
		Dr. William F. Raub Acting Director, NIH
DOE	James D. Watkins	Dr. James F. Decker Acting Director Office of Energy Research
DOEd	Lauro F. Cavazos	John T. (Ted) Sanders Under Secretary
EPA	William K. Reilly	Erich Bretthauer (Acting) Assistant Administrator for R&D
DOC	Thomas J. Murrin	Deborah Wince-Smith Assistant Secretary for Technology Policy
VA	Anthony J. Principi	Richard J. Greene, M.D. Assistant Chief Medical Director for R&D
NASA	Richard H. Truly	Kenneth S. Pedersen Associate Administrator for External Relations
NSF	Erich Bloch	Dr. Luther Williams Senior Science Adviser
DOS	Richard T. McCormack	Frederick M. Bernthal Assistant Secretary OES

DOD	George P. Millburn	Craig I. Fields Director, DARPA
DOA	Charles E. Hess	
HUD		
DOI	Dallas L. Peck	Dr. Harlan L. Watson Science Adviser to the Secretary of the Interior
DOL	Jennifer Dorn Assistant Secretary for Policy	Mr. Gary Reed Office Director, Office of Program Economics
DOT	Travis P. Dungan Administrator Research and Special Programs Administration	Joseph Canny Deputy Assistant Secretary for Policy
OMB	Robert Grady	
NSC	Eric D.K. Melby Director for International Economic Affairs	
DPC	Ken Yale Executive Secretary, DPC	
OSTP	Dr. J. Thomas Ratchford, Associate Director for Policy and International Affairs Dr. Karl A. Erb, Assistant Director for Physical Sciences and Engineering Ms. Sara Bowden Dr. Mary Harley Kruter Ms. Rachel Levinson	

THE WHITE HOUSE

WASHINGTON

February 26, 1990

MEMORANDUM FOR ALLAN BROMLEY

FROM: DAVID Q. BATES

SUBJECT: FCCSET and Science and Technology Policy

Thanks for your thoughtful letter of February 12 concerning the functions and activities of FCCSET and its draft charter. I have reviewed the materials with interest. You have properly identified several potential problems of coordination and possible duplication of functions with existing policy bodies, two of which the Office of Cabinet Affairs has direct responsibility for administering.

As you well know Allan, the President in signing the charter for the DPC and EPC clearly designated those two Cabinet Councils as the "primary channels for advising the President on policy." Early in the Reagan Administration there were six Cabinet Councils, each with a separate area of expertise and jurisdiction. That was changed in the summer of 1985 when it was discovered that the proliferation of policy bodies, all reporting to the President, invited Cabinet officers to "forum shop" their issues between and among the councils which would likely give them the best result. Thereafter all Cabinet-level policy formulation was to be done in one of three fora: the National Security Council, the Economic Policy Council and the Domestic Policy Council.

With the addition of the Space Council and recently the Competitiveness Council, there is growing concern that despite the President's early directive, we are in danger of repeating the mistakes of the past and undermining the positive benefit of the 1985 consolidation. That is why I am expressing some reserve in ratcheting up yet another "policy" body, albeit limited in scope to matters of science and technology. The fact that Congress has passed law establishing the FCCSET as a coordinating mechanism, does not mean that it can tell the President how to run his Administration.

I would recommend, therefore, some careful thought and deliberation before proceeding apace with a new charter for FCCSET. In fact, the EPC last year established a Working Group on Science and Technology with a broad mandate to examine federal policy in this area with an eye on U.S. competitiveness and sound economic policymaking. Unfortunately, that group has somewhat ground to a halt and just last week we spoke with Hollis

McLaughlin (Nick Brady's Counsellor) about revitalizing that effort under your leadership. I believe that Steve Danzansky mentioned this possibility to you. Treasury was most enthusiastic.

In that light, I have asked our staff to work with White House Counsel's office on how best to incorporate the work of FCCSET with the EPC/DPC process without jeopardizing executive privilege or subjecting ourselves to FOIA requests or congressional oversight. They are now looking into the matter and should have some answers within the next few days.

I would therefore counsel further consultation on the FCCSET question. Right now I would be leaning toward establishing an S&T Working Group in both the EPC and DPC under your leadership, with the former policy council looking at economic interface (e.g. competitiveness and industrial policy) and the latter focusing upon controversial domestic policy considerations (e.g. fetal research, medical experimentation, biotechnology, etc.). Perhaps the FCCSET effort could then be limited to an advisory or informational and coordinative role to protect the President from congressional intrusiveness.

I promise to be back with you shortly on these important questions and thank you for consulting with me in advance of proceeding.