U.S. Department of Justice

Environment and Natural Resources Division

Office of the Assistant Attorney General

Washington, D.C. 20530

March 12, 1991

MEMORANDUM

TO: Members of the Biotechnology Working Group

FROM: Dick Stewart DS
Assistant Attorney General

SUBJECT: Next Meeting of the Biotechnology Working Group

The Biotechnology Working Group ("BWG") of the Competitiveness Council will meet on Monday, March 18, 1991, from 10:30 to 12:00 noon, in OEOB 180.

Please provide your clearance information (full name and date of birth) to my office (phone 514-2701) by 12 noon on Friday, March 15.

The principal topics of discussion at the meeting will be:

- **Scope.** The "Scope," formally titled the "Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits," was proposed at 55 Fed. Reg. 31118 (July 31, 1990). Comments were received in autumn 1990. We now need to tabulate the comments and revise the Scope for final issuance.

- **Coordinated Framework Supplement ("CF Supp").** The BWG Report on National Biotechnology Policy (Feb. 1991) calls for an update by Spring 1991 of the 1986 CF to address oversight of new biotechnology research and products not in the 1986 CF (see Report at 14). Attention is needed to issues such as large-scale field release, commercialization, and new applications in the agricultural and environmental areas.

  For example, the CF does not adequately address the extent to which and how EPA, USDA, and FDA will oversee large-scale field tests and commercial sales of new crop strains with rDNA-implanted pesticidal properties, or the extent to which and how various agencies will address planned releases of microbes to clean up hazardous substance spills.

In light of the 1986 CF, the Four Principles of Regulatory Review, the "Scope" document, and new policy initiatives being prepared by agencies, the BWG will develop a "CF Supp" that addresses evolving areas of biotechnology applications. The CF Supp will shape the interagency coordination needed to allow economic growth and maintain US leadership while appropriately limiting risks to public health and the environment. The CF Supp should be completed by the end of June.

- **Orphan Drug Act.** Renewed Congressional action on Orphan Drug Act amendments is likely. Key agencies will report to the BWG at its next meeting.

- **International issues affecting US biotechnology.** Numerous issues need to be considered by the BWG, including:
  -- differences in regulatory approaches across nations and associated trade barriers or other effects;
  -- OECD efforts, such as the projects on Large-Scale Good Development Practices (GDP) and Food Safety;
  -- the Monsanto-led US-Japan Business Council effort to generate a consensus on the basis for regulation among US-Japan-EC players;
  -- international negotiations affecting biotechnology, such as the biodiversity convention, whose first round of formal negotiations has just concluded; drafts of the biodiversity convention have included a growing number of references to restrictions on biotechnology, access to genetic resources, and other issues.

In preparation for these discussions, it would be most helpful if you could provide to my office (fax 514-0557) by 12 noon on Friday, March 15, a very brief (one page) description of: (1) each major new or forthcoming policy initiative by your agency relating to biotechnology, such as new regulations; and (2) your agency's participation in international fora on biotechnology issues. These one-pagers will be for the internal use of the BWG, not for public distribution. Thank you.

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

FICE

March 13, 1991

MEMORANDUM FOR D. ALLAN BROMLEY

FROM: Rachel E. Levinson
RACHEL E. LEVINSON

SUBJECT: **COUNCIL ON COMPETITIVENESS, BIOTECHNOLOGY WORKING GROUP**

Next Monday, the Council on Competitiveness, Biotechnology Working Group will meet for the first time under its new chairman, Dick Stewart, Assistant Attorney General (announcement attached). As you will note, the first item on the agenda is the "Scope Document," which was published in the Federal Register for public comment last July, under your signature. Inclusion in the Working Group's agenda indicates that the Competitiveness Council perceives the document to be under their jurisdiction. It is my understanding that at this meeting, I will be tasked to develop a final version of the paper, which, in fact, I have been working on already. The question remains, who is to be held responsible for a final product?

This issue was discussed at an OSTP staff meeting with the conclusion that OSTP began this effort and would bring it to completion. I believe this to be appropriate. At the same time, in order to have any impact on the development of regulations, the Scope Document will need the blessing of the Council and OMB. Therefore, I would suggest that this topic might be raised at your meeting with Al Hubbard and Dave McIntosh, scheduled for Friday, March 15.

One option you might consider would be to state OSTP's intention to complete this piece, but in the future, consistent with the BRS focus on biotechnology research, OSTP's attention to regulatory issues will diminish. This is a shift from the Office's earlier position which was the central Administration locus for coordination of biotechnology regulation, hence its production and publication of the Coordinated Framework for Regulation of Biotechnology in 1986. Now, we have to decide if we are willing to see that role go to the Competitiveness Council. My own feeling is that as long as regulation is firmly based on the science, it does not matter who runs the meetings. This position rests firmly on the assumption that OSTP will continue to play a central role in the deliberations of the Council's Biotechnology Working Group.

Attachment

cc: **Dr. Ratchford**
Dr. Henderson

U.S. Department of Justice

Environment and Natural Resources Division

Office of the Assistant Attorney General

Washington, D.C. 20530

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Withdrawal/Redaction Sheet
(George Bush Library)

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION	CLASS.
01. Memo	Al Hubbard to D. Allan Bromley RE: attached article (1 pp.)	4/19/91	P-5	

Open on Expiration of PRA
(Document Follows)
By MB (NLGB) on 4/5/05

COLLECTION

Bush Presidential Records
Science and Technology
D. Allan Bromley Files

FILE LOCATION

White House Competitiveness Council

OA/ID Number 08720

Date Closed 5/19/00

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P-1 National Security Classified Information [(a)(1) of the PRA]
P-2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P-3 Release would violate a Federal statute [(a)(3) of the PRA]
P-4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P-5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
P-6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

Freedom of Information Act - [5 U.S.C. 552(b)]

F-1 National security classified information [(b)(1) of the FOIA]
F-2 Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
F-3 Release would violate a Federal statute [(b)(3) of the FOIA]
F-4 Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
F-6 Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
F-7 Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
F-8 Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
F-9 Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

FILE
Competitiveness
Council

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OFFICE OF THE VICE PRESIDENT

WASHINGTON

OFFICE OF THE DIRECTOR

April 19, 1991

MEMORANDUM FOR DR. D. ALLAN BROMLEY

FROM: AL HUBBARD AH

Attached is an article in Washington Technology on the Administration's biotech policy. The reporter's sources indicated that PCAST has a long debate on biotech and that the White House should spell out "goals for the industry." The member of PCAST might find the Vice President's report on biotech policy interesting in this regard.

Its main thrust is that private industry should be responsible for development of biotech products and not government, and that tax reforms such as redistributing capital gains and permanent R & D tax credit will take care of any market imbalance that creates pressure to seek foreign capital. This report is about as far as we want to go in setting goals.

Let me know if you would like my staff to brief PCAST on the Council's activities in this area.

Quayle Quizzes Swanson on Biotech Firm Sale

By Gene Koprowski
STAFF WRITER

Shortly after Genentech sold a majority interest last spring to Switzerland's Hoffman LaRoche, anxious White House aides summoned the biotech company's founder Bob Swanson to Washington for a serious talk with Vice President Dan Quayle, an official said.

Staffers from the Council on Competitiveness, an interagency panel that Quayle directs, demanded to know why the San Francisco-based company, viewed as the U.S.'s most promising biotech firm, didn't sell 60 percent of its shares to Merck or another American drug company, instead of a foreign competitor.

Swanson, a White House official said, told Quayle he would have preferred to sell out to an American firm—but that the U.S. tax structure for small research and development companies kept American firms at bay.

"It's a loss that is considered important," said Rachel Levinson, an assistant director of the White House science office during a briefing on Quayle's biotech report for the President's Council of Advisors on Science and Technology (PCAST). "They were a company that had the best chance of making it—of becoming a vertically integrated, large pharmaceutical company."

The loss of Genentech is still spooking the Bush administration nearly a year later. For unless changes in the tax code are made, officials believe the same thing could happen to scores of emerging high tech companies in many disciplines all over the U.S.

"This is an area where biotech is not unique," Levinson said. "The policies affect all of the innovative, small companies. They should not operate to the detriment of small companies."

Levinson said that the administration feels "tax policy is an area we can operate in immediately." At issue, specifically, is what accountants call "good will," she said.

The cost of employees can't be depreciated, as equipment can. Most countries have different tax codes that allow their companies to absorb this as good will, making the cost of doing business lower.

This so-called higher cost of capital forced Genentech to give up, even though it had many products waiting for approval by the Food and Drug Administration. Biotech industry officials agreed with the assessment.

The PCAST—in what White House staffers called its longest debate in memory—talked about the biotech industry's situation, and suggested the White House determine exactly what its goals for the industry are and how it wants to handle foreign competition. PCAST meets with President Bush to bestow its recommendations.

Panel member Norman Borlaug said future problems for the biotech industry will emerge if the Bush administration forges a free trade pact with Mexico or with Central American countries. "Each one of those countries has regulations on animal products," said Borlaug. "It's going to be a terrible mess." ◆

DAVE MIT

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

File

April 24, 1991

MEMORANDUM FOR D. ALLAN BROMLEY
D. A. HENDERSON
J. THOMAS RATCHFORD
EUGENE WONG
KENNETH YALE

FROM: WILLIAM D. PHILLIPS

SUBJECT: VICE PRESIDENT'S COUNCIL ON COMPETITIVENESS

It is the intent of the Vice President's Council on Competitiveness to release the attached late today (April 24) to coincide with the April 25 Senate and House hearings and release of the Critical Technologies Report.

The group putting this together was chaired by David McIntosh (with heavy John Cohrssen participation) and consisted of high level representation from OSTP, Treasury, CEA, HHS, NSF, DOD, DOC, etc. The material was basically lifted out of existing reports and studies, including OSTP's.

Considering where it started, this turned out reasonably well.

Attachment

OFFICE OF THE VICE PRESIDENT

WASHINGTON

April 24, 1991

MEMORANDUM FOR MEMBERS OF THE PRESIDENT'S COUNCIL ON COMPETITIVENESS

FROM: ALLAN B. HUBBARD
EXECUTIVE DIRECTOR

SUBJECT: COUNCIL FACT SHEET RELATED TO NATIONAL CRITICAL TECHNOLOGIES

The Council through its Working Group on Commercialization of Government Research has prepared a "Fact Sheet" describing the entrepreneurial climate for new and emerging technologies identified in the Report of the National Critical Technologies Panel that will be released tomorrow.

A draft of the "Fact Sheet" is enclosed. The "Fact Sheet" will be issued in final form at the close of business today so that it will be available concurrently with the release of the Report.

This draft has also been circulated to members of the Working Group to receive any final comments they may have.

Please call John Cohrssen at 456-2126 or fax 456-6231 with any final changes you might have to the Fact Sheet by no later than 3 PM today.

PRESIDENT'S COUNCIL ON COMPETITIVENESS

FACT SHEET

Achieving Competitiveness in National Critical Technologies

Policies in Support of Technology Development in America

"If America is to maintain and strengthen our competitive position, we must continue not only to create new technologies but to learn to more effectively translate those technologies into commercial products.

President George Bush
November 13, 1990

"For America to be number one in the development of critical technologies and commercialization of related products, we must have a healthy entrepreneurial climate for private sector development of these technologies."

Vice President Quayle
April 24, 1991

INTRODUCTION

1. The release of the Report of the National Critical Technologies Panel provides an important opportunity to restate those steps necessary to improve the U.S. entrepreneurial climate and maintain our competitiveness. While the American private sector is asked to invest in our future, the government must continue to remove those unnecessary government restraints that chill the climate for investment in new technology. The benefits of technology will bring us closer to the national goals of improved quality of life for all Americans, continued economic growth, and national security.

2. This Fact Sheet incorporates points made in previous Administration initiatives such as the critical technologies reports of the Department Defense and the Department of Commerce, U.S. Technology Policy prepared by the Office of Science and Technology Policy, and the National Energy Strategy. These policies encourage the development of technologies.

3. Critical technologies are fundamental "building blocks" for American industry and international competitiveness. Market

forces must be allowed to support their development, not selection and promotion by government.

The Free Market

4. The free market has served to make the United States the world's largest economy. The United States has a $5.5 trillion economy that achieves one-quarter of the world's production with 5% of the world's population. We are the world's leading exporter of goods and services, and the world's leading importer.

5. Creating and maintaining the proper entrepreneurial climate for national critical technologies depends on:

- o A quality workforce that is educated, trained, and flexible in adapting to technological and competitive change;
- o A financial environment that is conducive to longer-term investment in technology;
- o The translation of innovation into timely, cost competitive, high quality manufactured products;
- o An efficient technological infrastructure, especially in transfer of information;
- o A legal and regulatory environment that provides stability for innovation and does not contain unnecessary barriers to private investments in R&D and domestic production

The Private Sector Role

6. In the free market system it is the role of the private sector to identify and utilize technologies for commercial products and processes. Responsibilities of the private sector include:

- o Conduct R&D to advance industry-related knowledge and technology;
- o Identify and aggressively pursue potential commercial applications for technologies developed by private laboratories as well as by universities, Federal laboratories and foreign sources;
- o Increase quality, output, and productivity by undertaking necessary investments in physical capital;

- o Improve the skills and abilities of the private sector workforce to meet its own needs;

In addition, the private sector can participate cooperatively in improving the quality of U.S. education.

The Government Role

7. The government role is to foster a stable economic environment that is conducive to investment. Steady non-inflationary growth and adequate national savings are critical requirements for investment because investors need confidence in the future. Investment decisions should not be dominated by fears of erratic government policy, uncertainty in tax laws, or excessive or uncertain regulation.

8. The government role regarding critical technologies should be limited to (1) providing needed support to activities that are clearly undersupported by the market because they generate economic benefits that greatly exceed their profitability, and (2) removing unnecessary and artificial barriers to proper market functioning, including legal and regulatory barriers.

9. In order to assure that economic considerations determine allocations of resources in the market, the government should forego policies, tax laws, and practices that benefit specific industries, products or sectors in relation to others except where market externalities exist which prevent private sector investment from realizing full economic benefit of the investment. Actions that yield encouraging results for a particular industry create a larger cost to the economy in terms of reduced efficiency, productivity and standards of living.

ADVANCEMENT AND TRANSFER OF SCIENTIFIC KNOWLEDGE

10. Education, enhancement of technical knowledge in science, and the conduct of research and development in science and technology are responsibilities shared by government at all levels and a broad range of private organizations. Scientific literacy benefits all Americans.

11. The government helps to support research especially in situations where the private sector cannot reasonably be expected to recover sufficient benefits. Generic enabling technologies that cut across industries and at the precompetitive stage, often cannot be developed by individual firms acting solely on their own. Support also may be needed for areas where the private sector could not be expected to earn an adequate rate of return on its R&D investments because it would be unable to assert property rights if the research results were commercialized. This precompetitive research is often crucial to maintaining public health, safety, and national security.

Federal Funding

12. President Bush's budget proposal to Congress for FY '92 allocates $76 billion to R&D, an increase of 13 percent over FY' 91 enacted levels. Activities targeted for increases are examples of the types of areas where Federal support is appropriate:

- Basic research at the National Institutes of Health
- Basic research at the National Science Foundation
- Defense R&D
- Space activities
- Mathematics and science education
- Global change research
- Biomedical (including AIDS) research
- National Agricultural Research Initiative
- Superconducting Super Collider
- High-performance computing and communications
- Energy R&D
- Advanced manufacturing and materials R&D
- Aeronautics R&D
- R&D at the National Institute of Standards and Technology

Federal Technology Transfer

13. Technology transfer between Federally-supported researchers and the commercial market place is an important government function that offers fruitful opportunities for development of national critical technologies. Technology transfer conducted under cost sharing arrangements increases the benefits from Federal R&D expenditures and boosts government-private sector partnerships. The climate for technology transfer is enhanced by laws and arrangements that protect intellectual property rights and avoid conflicts of interest. Defense-related research can make major contributions when adequate safeguards for protecting information important to national security are available.

14. The 1980 Bayh-Dole Patent and Trademark Amendments Act permitted universities, nonprofit corporations and small businesses to retain patent rights resulting from Federally supported R&D. The Federal Technology Transfer Act of 1986 allowed Federally owned and operated laboratories to manage patentable rights. The 1986 Act also encourages directors of Federal laboratories to form joint R&D projects with businesses, universities and the states, and allowed Federal inventors to receive a portion of royalties resulting from commercialization of patents obtained from the research developed. Executive Order No. 12591 further mandated implementation of technology transfer by Federal agencies. In 1989 the provisions of the 1986 Act were

extended to the National Laboratories operated for the Department of Energy.

Federal Procurement

15. Because the U.S. government is the country's largest purchaser, spending nearly $200 billion for products and services annually, it can influence the development of commercial technologies. Government procurement practices generally should not dictate which technologies to use, rather firms should be able to compete to find the best way of meeting government's needs. In this way, government procurement practices should emulate the best commercial practices, allow government to participate to the greatest possible extent in the commercial marketplace, and take full advantage of the free market's ability to generate innovation.

16. Two special issues in Federal procurement are technical data rights and recoupment. Firms producing for the Federal government should be able to provide their best technical expertise without fear of its free release to their competitors. And firms should have the right to appropriately profit from the investment they make in commercial applications of technologies developed under Federal contracts. The government benefits from these practices through ready access to innovations occurring in the commercial market place, expansion of the industrial base supporting government activities, and price discounts recognizing the value of commercialization rights. The Administration will soon issue proposed regulations to ensure that government purchases only those rights and data required to meet the government's needs and to protect those it does not buy. The Administration is now reviewing the requirements to recoup R&D costs from contractors that develop commercial derivatives of products.

17. The Administration is pursuing a number of other changes in the Federal government's procurement practices that would contribute to technological innovation and development. Federal procurement statutes and regulations need to permit greater integration of government and commercial production at the factory level, as well as encourage greater innovation and efficiency in development and production. Also, the government should use commercial products, to the extent feasible, for defense, space, and other government applications. For those products and processes for which it is the sole or major consumer and no commercially available products can be substituted, the Federal government should (1) rely principally on the private sector to undertake the development process; and (2) strengthen the abilities of companies involved in developing and demonstrating these products to use the same research and technologies for commercial purposes.

THE LEGAL AND REGULATORY CLIMATE

Antitrust Concerns

18. Effective antitrust laws and their enforcement are crucial to the maintenance of a competitive economy, and thus to international competitiveness. Undue concern with antitrust enforcement should not, however, provide an unwarranted deterrent to activities that may in many circumstances enhance efficiency and competition. In particular, American firms should be assured that antitrust laws will not be applied in an overly restrictive way to joint ventures, including joint ventures among competitors, to engage in research and development of new technology, and to commercialize that technology. Reducing unwarranted antitrust uncertainties related to such interfirm cooperation would facilitate, where parties so desire, the pooling of limited resource and a rapid diffusion of results while still protecting against anticompetitive practices.

19. The National Cooperative Research Act of 1984 took an important step to mitigate antitrust uncertainty with respect to joint R&D. The Act clarified that R&D joint ventures should be analyzed under the antitrust "rule of reason," which takes full account not only of domestic and international competition to such ventures, but also of their potential procompetitive efficiencies. The Administration has proposed expansion of the NCRA to cover joint production ventures as well. Such ventures could promote the commercialization of new technology and help assure that United States leadership in basic scientific research is translated into leadership in commerce as well. At the same time, NCRA coverage of joint production ventures will permit the antitrust laws to play their proper role in preserving competition and thus the competitiveness of the American economy.

Intellectual Property Rights

20. Essential to the free market development of technology is the right of the private sector to maintain ownership of intellectual property rights of inventions at home and overseas. The Administration is aggressively pursuing improved international protection of intellectual property through the achievement of international agreements that would increase protections abroad in the Uruguay Round of the GATT, at the World Intellectual Property Organization and in trilateral talks with the European Community and Japan. Bilateral negotiations are also conducted under the provision of the 1988 Omnibus Trade and Competitiveness Act. The Administration also supports strengthened domestic patent protection.

Product liability

21. The current product liability system generates excessive litigation and concomitant transactional costs, thereby increasing the cost of doing business in the United States and discouraging innovation for products and related services such as health care. The Administration supports the adoption of a single, Federal, uniform product liability law based on three principles of fairness: the right to fair compensation for actual damages where there is liability, the remedy of liability based on responsibility for harm and not ability to pay, and the encouragement of alternatives to costly litigation. These proposals would maintain the appropriate incentives to produce safe products while restoring balance to the tort system and reducing uncertainty surrounding the introduction of new products.

Prohibitions on Competition

22. Clearly among the potentially most damaging aspects of government laws are prohibitions or restrictions on competition in particular markets. Competition drives the free market to optimal price and output for the benefit of consumers and society generally, and creates incentives for innovations and the means for new product introductions. When government erects barriers to market competition, it reduces the economy's flexibility, competitiveness and innovative capacity. In the energy area, for example, the Administration's National Energy Strategy calls for an end to unnecessary regulatory impediments to the expanded utilization of natural gas and innovative technologies for electricity generation. In telecommunications the Administration is seeking to change the antitrust consent decree that prohibits telephone companies from conducting R&D and manufacturing telecommunications equipment.

Export Controls

23. Export controls restrict the export of specific "dual use" products to certain destinations, for national security and foreign policy reasons. In an increasingly international economy, with rapid technological innovation in other countries, these controls require continuing revisions to ensure that the burden and delays associated with licensing do not adversely affect American firms relative to foreign firms in their ability to compete in international markets, and thereby, discourage R&D investments in the United States.

Non-Tariff Trade Barriers

24. Non-tariff trade barriers prevent open markets for international commerce, and thus, injure competition by reducing opportunities for new products, particularly high volume products such as certain electronic components. The U.S. is working through GATT, other multi-national and bilateral negotiations to

ensure that U.S. firms will be allowed to compete fairly in foreign markets. Private restraints on imports also can constitute significant non-tariff barriers to trade by American firms. Among the Administration's goals in the Structural Impediment Initiative talks with Japan is more effective enforcement of that nation's competition laws against private restraints on imports in Japan, such as group boycotts.

Regulatory Concerns

25. In high technology industries, Federal regulation is a critical determinant of the time and the cost required to bring a product to market. Regulation is also a major factor influencing investment decisions for new technologies. Regulatory uncertainty or the expectation of burdensome regulation increases risk for potential investors, and reduces incentives for investment. Because technological innovation holds the promise of providing new and better ways to meet the very objectives of particular health, safety, or environmental regulations, those regulations that discourage or penalize innovation are self-perpetuating burdens on American industry.

26. In general terms, Federal regulations impose direct costs on the economy of estimated to be $185 billion annually. While appropriate regulation in response to market failures can serve valuable social and economic functions, it may also impose significant costs that particularly affect the ability and incentive of firms to develop new high technology products. Some regulatory regimes are no longer appropriate to new technologies, others were developed without adequate consideration of the burdens placed on international competition, and many regulations explicitly impose greater burdens on new facilities and products, such as the New Source Review provisions of the old Clean Air Act and the rules for "new chemicals" under the Toxic Substances Control Act.

27. Regulation most inhibits innovation when the regulatory agency takes on the task of specifying which technologies or designs industry must employ. Further, once a technology is enshrined in regulation, firms have little incentive to invest in better techniques. This has been the experience with numerous environmental regulations in which the Federal government selects control technologies. An excellent example is the old Clean Air Act's mandate that firms employ "best available control technology" (BACT) to reduce SO_2 emissions. BACT was translated into smokestack scrubber technology. Mandating scrubbers, however, discouraged innovation of other means to remove sulfur, such as removal from the fuel before combustion; and it discouraged use of low-sulfur coal to begin with. The Administration's new Clean Air Act cuts SO_2 by 50% -- but lets industry choose how best to do so.

28. In general, regulatory reform can substantially improve the incentives for innovation by using market-based incentive approaches that set performance goals but let industry devise the best means to attain those goals. An example is the Administration's emissions trading program to reduce acid rain in the 1990 Clean Air Act.

29. The Administration has developed principles that Executive Branch agencies are to use when developing regulations or reviewing current standards. These principles offer a useful set of guidance for minimizing the burden of regulation on innovation.

- Regulations should be issued only on evidence that their potential benefits exceed their potential costs. Regulatory objectives, and the methods for achieving these objectives, should be chosen to maximize the net benefits to society.

- Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.

- Regulation of prices and products in competitive markets should be avoided. Entry into competitive or potentially competitive markets should be regulated only where it is clearly necessary to protect health or safety.

- Voluntary private standards and disclosure should be relied on where possible instead of inflexible regulation.

- Health, safety and environmental regulations should address ends rather than means. They should employ performance-based incentives that harness the creativity of market actors to design and continually innovate better ways of reducing excess risks. They should not specify technologies or designs that firms must employ.

- Where regulations create private rights or obligations, unrestricted exchange of these rights or obligations should be encouraged.

- Federal regulations should not preempt state laws or regulations, except to guarantee rights of national citizenship or to avoid significant burdens on interstate commerce.

- Regulations establishing terms or conditions of Federal grants, contracts, or financial assistance should be limited to the minimum necessary to achieving the purposes for which the funds were authorized and appropriated.

- Licensing and permitting decisions and review of new products should be made swiftly and should be based on standards that are clearly defined in advance.

- Standards for receiving government licenses and permits should not exceed the necessary minimum. If the number of comparably qualified applicants exceeds the number of available licenses, the licenses should be allocated by auction or other market-based means rather than by administrative procedure.

THE FINANCIAL CLIMATE: INCREASING THE POOL OF CAPITAL FOR INVESTMENT

30. Recent Federal policy has been successful in improving the environment for private investment in R&D. Important actions have been taken to increase incentives to invest, including investment in R&D. The Tax Reform Act of 1986 substantially reduced marginal income tax rates for businesses and individuals. The maximum tax rate on corporate income dropped from 46% to 34%. The top personal income tax rate that had been 70% as recently as 1981 was dropped to 28% in 1986 and increased to 31% in 1990. "Subchapter S" corporations generally can pass through their income to shareholders and have it taxed at lower individual tax rates and avoid the double taxation of corporate income.

31. Discipline must be maintained to curb the Federal budget deficit. The single greatest contribution that the Federal government can make to increase the pool of capital available for investment is to reduce the Federal budget deficit. The budget deficit has a major impact on the level of gross domestic savings available for investment. Efforts to reduce the Federal budget deficit (the Omnibus Budget Reconciliation Act of 1990) and to impose Federal credit programs (Federal Credit Reform Act of 1990) will increase the availability of national savings for private sector uses, including investment in new technology. The Omnibus Budget Reconciliation Act of 1990 will reduce Federal budget deficits, and therefore national dissaving, by almost $500 billion over the next five years, and will virtually eliminate the Federal budget deficit by fiscal year 1995. In addition, better control of the deficit enhances the opportunity for the Federal Reserve to pursue a noninflationary growth monetary policy.

32. Through the use of guarantees and interest rate subsidies, the Federal Government redirects credit in the economy to certain favored activities. In doing so, non-favored activities in the economy are penalized and the efficiency of the resources available to the economy is reduced. The Federal Credit Reform Act of 1990 places the cost of credit programs on the same budgetary basis as direct Federal spending. For 1991 it is estimated that direct Federal loan guarantees will total $119 billion and direct Federal loans will total $16.8 billion; these exclude secondary loan guarantees. Discipline will be needed to constrain the growth of Federal credit programs.

Increased Savings

33. A larger pool of capital also would be assured if proposals advanced by the Administration are enacted. These include the capital gains tax cut, family savings accounts and enhanced IRAs. Failure to act on these proposals will have a negative effect on national savings and the availability of capital for investment.

34. Pressures to increase Federal expenditures continue for a wide variety of purposes and programs. This has led to proposals to raise marginal tax rates for upper income individuals and corporations. Higher marginal tax rates reduce the return from investment. If Federal actions discourage investment, inevitably economic growth will suffer. The Administration will continue to resist pressures to raise marginal income tax rates.

Research and Experimentation Tax Credit

35. The Administration has proposed to make permanent the Research and Experimentation (R&E) tax credit. Current law allows a 20% tax credit for a certain portion of a taxpayer's qualified research expenses. The credit is computed on the increase in qualified expenses compared to a base period. The credit will expire at the end of 1991 unless it is extended or made permanent. A permanent credit would provide more certainty for firms regarding the availability of the credit as they make investment plans for future years. The credit cannot induce additional R&E expenditures unless its future availability is known at the time firms are planning future outlays. Thus, to have its intended incentive effect, the credit should be permanent.

R&E Expense Allocation

36. The Administration has proposed a change in the rules for allocating R&E expenses on foreign source income for the purpose of computing net income from foreign sources. Under the proposal, there would be a lower allocation of U.S. R&D against foreign source income than required by the original 1977 regulations. For companies with unused foreign tax credits, the

lower allocation would permit them to take a larger foreign tax credit, and thus, lower their U.S. tax liability. The provisions will expire at the end of this year unless extended by law.

Banking Reforms

37. The financial system has been undergoing change in recent years as a result of deregulation, increased competition from non-traditional sources and international competition. Yet, America's depression era banking laws inhibit the ability of financial institutions to respond to this changing environment and they encourage excessive risk taking by banks. This has led to unhealthy lending practices in some instances and, in general, the banking system is now restricting loans to many borrowers. While tight lending practices of the banks affect all potential borrowers, we should not overlook the fact that start-up companies and firms that are developing new products or attempting to bring them to market may be particularly hard hit in a tight credit environment. The Administration's proposals would improve the health and flexibility of the banking system. Of course, banking system reform should not hinge on improving credit availability just for R&D; still those who are concerned about the availability of capital for R&D should recognize that there is a connection between restoring the health of the banking system and the availability of capital for research, development and competition.

File

COORDINATION OF COUNCIL ON COMPETITIVENESS, OSTP/FCCSET AND DOC ON TECHNOLOGY TRANSFER AND COMMERCIALIZATION OF FEDERAL RESEARCH

OVERALL GOAL: Maintain competitiveness of US technologies
- -enhance commercialization of Federal research
- -identify barriers and incentives to commercialization of technologies

Current work plan

1. FOIA. An examination of FOIA with a view to identifying available administrative approaches to avoid chilling effects on Federal-private sector research and technology initiatives. DOC has begun a preliminary draft.

2. Conflict of interest. An examination of conflict of interest requirements to identify methods of avoiding conflicts while encouraging collaboration between Federally supported researchers and private researchers. Initial discussions at early Working Group meetings would need a lead agency and follow-up for further action.

3. Evaluate the technology transfer infrastructure to better leverage Federal, state, university and private resources for technology transfer. Federal laboratory missions and private sector needs are seen as mismatched. The NES refers to a new national laboratory initiative. The Council and DOE propose that the Council Working Group on Commercialization of Technology continue to take the lead for this activity.

New Initiatives

4. Evaluate regulatory barriers and incentives to maintaining competitiveness in critical technologies using the National Critical Technologies Report as a guide to technologies of greatest concern. OSTP oversaw the Panel that developed the Report. The Council proposes a joint activity with OSTP and the Council Working Group to assess government imposed barriers to development of the technologies identified in the report (and possible R&D tax incentives).

5. Create incentives to encourage "cultural change" to enhance better support of technology transfer activities. This involves improving the climate in Federal laboratories to encourage technology transfer. Part of these activities are underway through DOC's interagency committee that oversees implementation of the Federal Technology Transfer Act. We propose that DOC continue these activities and report to the Council Working Group.