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Richard Porter

June 16, 1992

Richard:

Attached is a copy of a speech I recently delivered where your boss is mentioned in several places. I just thought you might be interested. I also sent copies to Bill Kristol and John Cohrssen

Your office is doing a great job! Keep up the good work!

Ken Yale

NATIONAL BIOTECHNOLOGY POLICY

The Bush Administration, a Year in Retrospect

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NATIONAL BIOTECHNOLOGY POLICY

The Bush Administration, a Year in Retrospect

Executive Summary

I. Introduction

The Bush Administration is a strong advocate of the importance of biotechnology as an investment in our future, and as a stimulus for economic growth and improvements in the quality of life. The United States has been the leader in research, development, and commercialization of biotechnology. The past year has seen much activity in the Bush Administration to refine and implement the National Biotechnology Policy to ensure the United States retains its preeminent position in biotechnology. The National Biotechnology Policy was first announced by the Vice-President in February of last year. That policy guidance presented three areas of emphasis: science and technology, sensible regulations, and financial incentives.

To move forward in these three policy areas the Administration has continued to push for more funding, develop risk-based regulations that protect safety without unnecessarily burdening industry and economic growth, and encourage capital formation and the protection of intellectual property rights. Efforts to provide a supportive research, regulatory and financial climate for new innovations and economic growth will continue as new challenges emerge for the biotechnology industry. Following is a discussion of some current Administration

efforts in biotechnology.

II. Biotechnology Policy

A. Overview. The Bush Administration is moving forward in many areas, including biotechnology research, government to industry technology transfer, interagency coordination, regulatory reform, and intellectual property protection.

B. Science and Technology. Investing in our future has been a major theme of the Bush Administration. This interest can be seen in the emphasis on biomedical and behavioral research. The amount requested in the FY 1993 budget for health related research was $10.6 billion, a 35 percent increase over the amount appropriated in FY 1989.

Biotechnology Research Initiative. A coordinated research effort was announced by the President as part of his FY 1993 budget proposal. The initiative was developed by a new Federal interagency group that will continue to provide oversight and coordinate activities of twelve Federal agencies involved in biotechnology related research, through the Federal Coordinating Council on Science, Engineering and Technology. The Biotechnology Research initiative is a $4 billion program intended to help extend U.S. leadership in biotechnology and research related to health, manufacturing, bioprocessing, energy and the environment.

C. **Regulatory Reform**.

1. **Overview**. Regulatory reform is a major initiative in the Bush Administration. Excessive regulation poses additional costs and is like a hidden tax. The cost of complying with Federal regulations is estimated to be $300 to $500 billion annually. This can be a formidable obstacle, especially for small biotechnology companies. Under direction of the President, the Vice-President is leading an initiative to stop regulations that hinder economic growth and speed up new rules that help biotechnology industries and our Nation's economy. A moratorium was imposed to review regulations under development. The moratorium has been extended and there will be continued oversight to reduce unnecessary and overly burdensome regulations. Two actions specifically related to biotechnology include release of the "Scope" guidelines on biotechnology products and drug approval process reforms.

2. **"Scope" Guidelines**. A statement of principles for the release of biotechnology products into the environment was issued earlier this year. The principles require that Federal agencies exercise regulatory oversight only when a biotechnology product poses an unreasonable risk. This so-called "scope" document is intended to guide the development of regulations and is the culmination of years

of work among the Federal agencies. The guidelines will also assist with the coordination of biotechnology regulations among Federal agencies. A number of follow-up steps will be taken to implement the guidelines, including a review of new rules affecting biotechnology products and development of "road-maps" to inform individuals and companies of routes to take in the Federal regulatory agencies to obtain approval of biotechnology products.

3. **Drug Approval Process**. Reforms of the drug approval process in the Food and Drug Administration (FDA) were announced this year. These reforms are intended to reduce the approval time at the FDA for new drugs, to save lives, and to enhance the competitiveness of the American pharmaceutical industry. Under the initiative: 1) certain drugs will receive accelerated approval, 2) a "parallel track" will allow the distribution of promising new drugs to patients outside of FDA mandated clinical studies, 3) external review outside of the normal internal FDA process will be sought for certain drugs, 4) the FDA will better coordinate animal test data to avoid multiple and duplicative studies, and 5) goals have been set for the FDA to expedite the review and approval time and reduce the backlog.

4. **Capital Market Reforms**. A number of reforms were developed to increase access to capital and eliminate unnecessary regulatory burdens. Streamlined securities registration forms will reduce the

cost of initial public offerings for eligible small biotechnology companies. Other reforms simplify reporting and disclosure requirements and make it easier to obtain capital for business expansions.

D. Financial Incentives.

1. **Overview.** The Administration has taken steps to improve the economic climate for biotechnology industries. In addition to reforming regulations, proposals have been initiated to make permanent the research and experimentation tax credit, reduce the capital gains rate to encourage investments, and improve intellectual property protection through process patent legislation.

2. **Human Genome Research.** The Federal government funds much intramural and extramural research, including research into the human genome. Federal government agencies are also responsible for the free flow of scientific data and information and to encourage the transfer and commercialization of the results of the Federal investment into research. The National Institutes of Health has applied for a U.S. patent on certain findings related to research into the human genome which it has funded. This application has raised concerns about technology transfer from Federally funded genome research. To address these concerns the Federal Coordinating Council on Science, Engineering and Technology has formed a

Genome Patent Working Group. This groups is in the process of considering a coordinated Federal interagency policy on intellectual property and technology transfer issues arising from Federally funded genome research.

3. **Orphan Drug Act**. The Orphan Drug Act of 1983 provides incentives for the development of drugs for rare diseases that might not otherwise be developed because of the small patient population (under 200,000), limited sales and low profit potential. Incentives in the Act include tax credits and seven year exclusive marketing rights. The law has encouraged research and development of innovative drugs to treat rare diseases.

Congress decided to amend the Act in 1990 due to sizeable profits generated by some drugs with the orphan designation. The Administration opposed legislation that would retroactively remove rights assigned under the Act and it encouraged the FDA to improve implementation of the law to better focus on orphan diseases. This year the Administration reiterated its interest in encouraging the development of orphan drug innovations and opposing attempts to weaken the Act.

III. Policy Development and Implementation

A. A View from the White House. Policy development and implementation in the White House is a mix of planning, coordination, negotiation, problem solving and legislative strategy. In proceeding with the development of new laws and policies, current Federal policies, regulations and laws must first be reviewed. The interests of all Federal agencies with a legitimate interest are then coordinated in an interagency group, such as the Policy Coordinating Group. Differences are negotiated and a determination is made on whether to establish a new policy or law. This phase requires an understanding of the legal climate, policy implications, and the current political realities. Once it is determined that a new national policy or law will be pursued it is then a matter of resolving differences between rival government interests and their private sector counterparts, and developing a strategies to push legislation through the Congress.

B. Policy Development and Coordination.

1. Overview. Federal technology policy is developed through a variety of processes, some highly structured, others less structured. These include legislatively mandated entities, ad hoc groups -- so called IAGs, for "interagency groups," formal Cabinet Councils, working groups and task forces. Each of these has different legal requirements and restrictions and all blend public and private sector perspectives and balance Executive branch and Congressional

interests. Sometimes, groups subject to the greatest restrictions, under the sunshine laws, the Federal Advisory Committee Act, or the Freedom of Information Act, may be the least effective in developing significant policy, regulations or legislation. Although formal processes can be a source of information for Federal officials, the work of the Federal government takes place through formal processes, informal interactions, and ad hoc groups.

2. **Biotechnology Policy**. The 1986 Coordinating Framework for Regulation of Biotechnology outlined the regulations for companies to follow in research and development of biotechnology products. The Biotechnology Science Coordinating Committee (BSCC) was also created in 1986 under the Office of Science and Technology Policy. The members of that committee came from Federal agencies with regulatory authority over biotechnology. The BSCC fulfilled a scientific coordinating function, however it was controversial as a senior level policy body because of closed meetings and lack of reporting relationship to a higher policy body, which created a stalemate whenever a controversial issue was reached (such as environmental release of biotechnology products). Eventually the BSCC was mired in controversy, with agency officials refusing to attend meetings and the committee subject to Congressional inquiries.

Congress wanted better access to internal Executive branch deliberations and more public involvement, so they created the National Biotechnology Policy Board, an interagency policy board with private sector membership. The Office of Science and Technology Policy created the Biotechnology Research Subcommittee -- the successor to the BSCC. The activities of this group were limited to fact-finding, interagency coordination, reporting and serving as a clearinghouse for information related to biotechnology. The President's Competitiveness Council took up the issue of regulatory reform. The Biotechnology Working Group under the Council developed the National Biotechnology Policy document, coordinated the "scope" document for environmental release of biotechnology products, and will continue to play a role in the oversight and review of regulations affecting the biotechnology industry, including the anticipated FIFRA and TSCA regulations.

3. **Example**. The pocket veto of the Orphan Drug Amendments of 1990 is an example of the Executive Branch policy process. Congress wished to amend the Act in 1990 because some orphan drugs had generated sizable profits. Legislation was introduced, hearings were held and an intense lobbying effort ensued. Congress and the Administration were deluged with facts and figures and the legislation was finally passed in both the House and Senate

after development of a carefully crafted compromise. However, the legislation was pocket vetoed after it was determined that it violated principles established by the Administration through an interagency process that included the Biotechnology Working Group in the Competitiveness Council, the Office of Science and Technology Policy, and the Office of Management and Budget. These groups sought the advice of the affected private sector entities and decided to recommend the President veto the bill.

IV. New Challenges on the Horizon

A. The Orphan Drug Act. Efforts will continue to restrict the incentives to innovate provided by the Orphan Drug Act. Legislation has been reintroduced in the current Congress. The Administration has expressed opposition to this legislation. Nevertheless, compromises could be reached and legislation passed this year.

B. International Competitiveness. A recent report by the National Research Council of the National Academy of Sciences warns of potential threats to the U.S. biotechnology industry from Japanese companies. Several problems were cited in the report, including exploitation of U.S technology by Japanese companies, lack of U.S. market share in Japan and other countries, and the importance of increased government, university, and industry actions to prevent further erosion of the U.S. position. The report

also recommended the U.S. government consider changing to a "first-to-file" patent system. Increasing industry participation and activism in Federal government policies will assist in moving Federal government biotechnology policy forward to meet these new challenges.

C. **First-to-File**. Legislation has been introduced in the House and Senate to change the United States patent system from a "first-to-invent" system to one that is based on "first-to-file." Hearings have been held, but it is unlikely that the legislation will pass this year due to the abbreviated election year Congressional calendar. Nevertheless, Congress will continue to consider this legislation next year and it is very likely to meet with increasing interest.

D. **Biodiversity**. The United Nations Conference on Environment and Development is scheduled to meet in plenary session in early June 1992. The conference will consider international environmental and economic development agendas into the next century. Technology transfer policies are a major item in draft treaties scheduled for signature at the conference. A biodiversity treaty is being prepared that has as its broad goals the preservation of plant and animal diversity through the conservation of ecosystems. However, treaty language would also require the transfer of biotechnologies to developing countries irrespective of existing intellectual property rights. Furthermore, the treaty would restrict international biotechnology trade. Developing countries will continue to press for free or inexpensive transfer of technology from developed countries, both during

and after the conclusion of the conference in June. The Bush Administration and other industrialized countries have expressed their opposition to this treaty language and the President has indicated that he will not sign any agreement that is harmful to U.S. businesses or the economy. This is consistent with the commitment of the President to wise stewardship of our planet and sound environmental policies, the promotion of economic growth and development, and improving the quality of life for all peoples.

E. **Health Care Reform**. Pressure is growing in both the public and private sectors for solutions to problems with access to health services and increasing costs. Health care is now at the top of the political and policy agenda. Some advocates of reform believe that new technologies and unnecessary procedures are major components of the unrestrained growth in health care costs. Any effort to reform the health care system, even if it only focuses on changing consumer or provider behavior, will also affect technology if it results in restrictions on reimbursement. The potential conflict between the public's desire for the best technology and cost concerns will grow with the debate over health care reform. The emphasis could shift, from wanting the best medicine to seeking the best bargain. The challenge is to move forward into a new world of health care reimbursement and not allow the benefits of new technologies to be lost in the rush to find solutions to fiscal problems.