

**NLWJC - Kagan**

**Counsel - Box 026 - Folder 007**

**Counsel: Regulatory Working  
Group 1995 [2]**



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

ADMINISTRATOR  
OFFICE OF  
INFORMATION AND  
REGULATORY AFFAIRS

STATEMENT OF SALLY KATZEN  
ADMINISTRATOR  
OFFICE OF INFORMATION AND REGULATORY AFFAIRS  
OFFICE OF MANAGEMENT AND BUDGET  
BEFORE THE  
SENATE COMMITTEE ON THE JUDICIARY  
SUBCOMMITTEE ON ADMINISTRATIVE OVERSIGHT AND THE COURTS

February 22, 1995

Good morning, Mr. Chairman and Members of the Subcommittee. I am pleased to be here today to discuss with you S. 343, the "Comprehensive Regulatory Reform Act of 1995." The Administration looks forward to working with you in the coming months as we both engage in efforts to improve our regulatory system.

The stated goal of S. 343 is to produce a more rational rulemaking process by increasing the opportunities for public involvement, by focusing agencies' attention on the consequences of their regulations, and by requiring central Presidential review of important new regulations. These are laudable goals, which the Administration fully and actively supports. Indeed, we have spoken frequently and forcefully of the importance of basing regulatory decisionmaking on good data and good analysis of costs, benefits, and risk, of the importance of centralized regulatory review, and of the desirability of an open and transparent process. More importantly, we have done a great deal to put these ideas into practice, beginning almost immediately after we took office.

Executive Order No. 12866, which President Clinton signed on September 30, 1993, represents the cornerstone of our efforts. It recognizes that there is an important role for regulation in protecting the health, safety, environment, and well-being of the American people. At the same time, it emphasizes that Government

has a basic responsibility to govern wisely and carefully, regulating only when necessary and only in the most cost-effective manner.

To implement this philosophy, the Order sets forth principles emphasizing the critical role of analysis (of costs, benefits, and risk) and of the use of that analysis in decisionmaking; consideration of different regulatory alternatives and of alternatives to regulation; the importance of private markets and the use of market incentives in regulating; the need for performance standards rather than command and control techniques; better consideration of the needs of small businesses and the roles of state and local governments; and the need for extensive consultation with all those affected by the regulation (both those who will benefit and those who will be burdened). The Executive Order requires agencies to propose or adopt a regulation only after determining that the rule would achieve its objective in a cost-effective manner, and that its benefits would justify its costs. The Executive Order also charges my office with reviewing all significant Executive Branch agency rules in order to ensure that its principles are satisfied.

Recognizing that risk and cost/benefit analyses are valuable tools in helping agencies make regulatory decisions in a sensible and cost-effective manner, the Administration has expressed its support for legislation in this area that is fair, effective, and affordable. But we do not support legislation that is likely to burden the regulatory process with unnecessary or costly requirements that will cause delay and gridlock, or likely to have substantive consequences that are detrimental to the American people.

We have reviewed S. 343 and very much regret that it does not appear to live up to these standards, nor to its own

professed standards of regulatory efficiency. To the contrary, as drafted, S. 343 is subject to the same criticism often leveled at the existing regulatory system it is seeking to fix -- too broad, too prescriptive, and fraught with consequences that threaten to impede, entangle, and further bureaucratize important functions of government. Let me describe some of these problems.<sup>1</sup>

**Section 621 -- the Definition of "Major Rule."** One obvious problem with S. 343 is its scope. Its regulatory impact analysis requirements apply to each "major rule." A major rule is then defined as one that "is likely to have a gross annual effect on the economy of \$50,000,000 or more" or is likely to result in "a substantial increase in costs or prices" for everyone in our society or has "significant adverse effects" on competition, employment, investment, innovation, the environment, public health or safety, etc.

These open-ended phrases, once written into statute, to be interpreted by the courts, could sweep in an enormous number of regulations that do not warrant, and could not conceivably profit from, a full-blown cost/benefit analysis. Is there a "substantial increase" in price if there is a 5¢ increase in a 15¢ item? A 5¢ increase in a \$1.00 item? What if you use a 1,000 of those \$1.00 items? Is it still "substantial" if the 1,000 items account for less than 1% of your cost of service? Where is the line to be drawn? How are the agencies to know where it should be drawn and what criteria would be used by the courts in reviewing whatever decision is made?

---

<sup>1</sup> There are a some confusing aspects of the bill as introduced, such as cross-references to a Subpart III that does not exist, and amendments to the Regulatory Flexibility Act that I am not discussing here.

Even where there is a clear line established -- i.e., namely, the \$50,000,000 threshold -- that clear line is highly questionable in light of the experience of the last 20 years. Since President Ford, every President has had an executive order establishing regulatory review. An essential ingredient of these orders is a distinction between that which is important and that which is more routine or administrative. For over 20 years, that distinction has been drawn at an aggregate annual effect on the economy of \$100 million.

In developing Executive Order No. 12866, the Administration consciously retained \$100 million as the threshold for requiring a cost/benefit analysis, having determined that the resources devoted to regulatory analysis should be commensurate with the significance of the decision to be made. Allocating resources where they are most productive (i.e., getting the biggest bang for the buck) is a tenet of proponents of cost/benefit analysis. But by setting the threshold for such analyses at one half of what President Reagan used in his Executive Order, S. 343 dilutes this distinction. Indeed, for a large number of rules, there would be newly imposed procedural and paperwork requirements that can only cause delay and gridlock.

**Section 623 -- "Decisional Criteria."** S. 343 provides that no final major rule can be issued unless the agency finds that the potential benefits of the rule "outweigh" the potential costs of the rule and that the rule will provide greater net benefits to society "than any of the reasonable alternatives" identified during the rulemaking process. To be explicit on the intended effect of this provision, the language goes on to state that unless an existing statute "contains explicit textual language prohibiting the consideration" of these decision criteria, these criteria "shall supplement the decisional criteria for rulemaking" under the statute authorizing the rulemaking.

The potential effects of Section 623 are hard to itemize, but the significance of the contemplated change cannot be overstated. For more than 30 years, Congress has passed -- and Presidents from both parties have signed -- publicly acclaimed legislation for which the decisionmaking criteria are different from that suggested here. Some legislation -- much of it seeking to redress long-standing wrongs to minority groups and persons with disabilities -- is based on social and procedural, rather than economic, standards of equity, fairness, and due process. Other legislation -- including legislation involving safety to workers -- reflects Congressional judgments that significant occupational hazards should be eliminated if economically feasible. Still other legislation -- much of it designed to protect the environment -- is based upon standards tied to the most advanced technology being used by industry. And other legislation -- underpinning entitlements, benefits, and formula grant programs -- views certain individuals and groups as worthy of society's support exceeding a level that a marginal analysis of aggregate social needs might suggest.

All of this legislation was vigorously debated and carefully considered at the time of enactment, and it has served as the underpinning of American society since at least World War II. It may be appropriate to review and/or reconsider some of these decisions, but any changes in underlying standards should be debated and decided on the merits and not in the guise of procedural reform. To override all of this history in 21 lines of text, without identifying the statutes and regulatory programs involved, and without a reasoned discussion by the responsible Committees and by the full Senate and House of the myriad of social and economic policies that are implicated cannot be fairly characterized as good government.

**Sections 624 and 628 -- Judicial Review.** Adding to this potential chaos is the explicit provision that agency compliance

or noncompliance with these decision criteria is subject to review in the Federal courts.<sup>2</sup> Each regulation issued under an existing statute (with its own decision criteria, agency practice, and court precedent) would become subject to these new decision criteria. For present purposes, the important point is that the bill (specifically Section 624(d)) makes Federal judges, rather than the Congress, responsible for deciding what changes in social and economic policy are to be made.

Consider also the provision for judicial review of the determination of whether or not the rule is a major rule to which these criteria are applicable. As I noted above, the open-ended definition of "major" invites endless opportunities for litigation, producing uncertainty and delay with all of the attendant costs. Again, the Federal judges are being asked to focus on whether the agencies choose the right path to follow in developing a rule rather than a review of the rule on the merits.

We are also troubled by Section 628, which requires a reviewing court "applying traditional principles of statutory construction" to look to whether the agency has applied the "interpretation of the statute intended by Congress," and if the statute gives the agency discretion to choose from among a range of permissible statutory constructions, to choose the interpretation "that maximizes net benefits to society." As this Committee well knows, there is an enormous body of law and lore on the subject of statutory construction and on the more arcane issue near and dear to the hearts of administrative lawyers on the subject of an agency's interpretation of its statutory

---

<sup>2</sup> Section 624 is reinforced, in Section 628, by having the Federal court favor, within the "range of permissible statutory constructions" considered by the agency, the "one that maximizes net benefits to society."

mandate. It is far from clear what changes to the Chevron<sup>3</sup> decision are being made, what other seminal administrative law decisions are being overturned or significantly modified, and, again, what the implications will be for the host of organic statutes whose interpretations (by the agencies or by the courts under a different standard of review) have up to now been considered settled law. These are matters that should not be lightly brushed aside, particularly in the name of improving the regulatory system.

Also, to the extent that the agencies (and the courts) are locked into the intent of Congress, the weight will likely be given to the intent of the Congress that passed the statute -- 10, 20, 30, or more years ago -- augmented by the intent of subsequent Congresses only to the extent they have manifested that intent in the form of amendments, riders, etc. What will be the weight accorded the oversight process in the more recent past, currently, or as it may be expressed in the future? Is it really the will of the Congress to instruct the Federal judiciary to ignore the results of this traditional and highly effective Congressional oversight process?

**Section 626 -- Comprehensive Report and Wait.** Our concerns with Section 626 focus in the other direction -- on improper interference in the Executive's responsibility to implement the law. Section 626 provides that, subject to certain limited exemptions, any major rule is to lay over in Congress for 45 days awaiting, under expedited procedures, a potential legislative override. While Section 626 purports to restore power to the Congress to stabilize the balance of power, it could in fact raise serious Constitutional questions.

---

<sup>3</sup> Chevron v. NRDC, 467 U.S. 837 (1984).

I need not belabor the Constitutionally established separation of powers: Congress -- the Legislative branch -- authorizes the Executive branch to carry out designated responsibilities. The Executive branch is responsible for the day-to-day decisionmaking -- the conduct and fulfillment of these Federal responsibilities. To oversee these day-to-day activities, Congress -- its Committees, its leadership, its individual Members -- retains well-established mechanisms of formal and informal oversight.

But in Section 626, the Congress will put itself into the position -- for 45 days -- to have individual Members, their staff, and any private constituents whose help they request scrutinize the agencies' work product. Will some suggest "modest changes" if the agency wants its rule to go forward? Will others suggest the addition (or deletion) of one "small piece" of the proposed package? This is a very significant handle to give an individual Member -- or his or her staff -- and it will virtually ensure that the lobbying on particular regulations (which can be quite intense) will now move from the agency -- where the often competing claims are to be reconciled -- to the Hill, where there is neither the time nor the resources to verify information, hear the "other side of the story," or resolve the conflict. And this intervention would take place at the end of the process and without any of the disclosure and record requirements set forth in the Administrative Procedure Act, which stresses openness, accountability, and due process for all.

In addition, Section 626 provides for the suspension of all statutory deadlines, and deprives the Federal courts of jurisdiction based on any such deadlines, until all the requirements of this law are met. Again, with a few lines of text, a host of statutes will be amended without identifying which they are and without consideration having been given to why

in each instance an earlier Congress chose to impose such deadline.

**Section 625 -- Look-Back.** Section 625, "Petition for cost-benefit analysis," provides that anyone may petition for review of an existing major rule if he or she believes it does not provide "greater net benefits to society than any reasonable alternative to the rule," and then the agency must conduct a detailed cost/benefit analysis as provided in S. 343. As a matter of principle, this Administration supports -- indeed, encourages -- agencies to review the effectiveness and efficiency of existing rules -- particularly those that have been on the books for a number of years. But Section 625 is unworkable and, if enacted as drafted, could transfer the management of the agencies from both the Executive and Legislative branches of government to special interests pursuing their own agendas.

Section 625 authorizes individuals to file a petition to have an agency review a major rule, any portion of a major rule, or agency guidance or general statement of policy that is equivalent to a major rule. The agency is to decide whether there is "a reasonable likelihood that the costs ... outweigh the benefits or that reasonable questions exist as to whether the rule provides greater net benefits to society than any reasonable alternative ...". If the agency denies the petition, that action is immediately reviewable in court. If the agency grants the petition, it must promptly undertake the requisite cost/benefit analysis of the subject of the petition. And for certain categories of petitions, the agency is prohibited from enforcing the regulatory requirements until that analysis is complete.

There is little in the field of regulation that would not give rise to some "reasonable questions." Moreover, since the threshold for defining a "major" rule would be half of what it has been for the past 20 years (without even taking account of

inflation), there are undoubtedly a very large number of regulations that have never been subject to the requisite cost/benefit analysis.

The task, therefore, facing the agency may be formidable. The time pressure would likely be impossible to meet. But most significantly, the agency's task will not be determined by the President or the people he appoints, or by the Congress. Rather the priorities for the agencies will be set by the special interests who are the first to flood the agencies with their petitions and sufficiently well-financed to keep the petitions coming.

There are several other concerns that we have with S. 343. For example, Section 627 prohibits, "notwithstanding any other provision of law," any rule "that expands Federal power or jurisdiction beyond the level of regulatory action needed to satisfy statutory requirements." Depending on how one interprets the word "requirements," this could be applied to nullify any effort by an agency, despite any statement of original Congressional intent, to go beyond the bare minimum of what is explicitly required in the statute. Similarly, the language of Sections 652 and 653 is problematic in that S. 343 assumes that the reviewing entity will have serious substantive responsibilities but only provides 30 days in which to carry them out. These may well be issues of drafting, rather than of differences in objectives, that can easily be resolved.

\* \* \* \* \*

I regret that I have spent so much time speaking to matters on which we disagree rather than on the areas where we agree. The current regulatory system needs improvement. This Administration has stated (well before the most recent election - indeed, since its inception) that there are too many

regulations, that many are excessively burdensome, that many do not ultimately provide their intended benefits, and that, consequently, many members of the public are justifiably frustrated and angry with the federal regulatory system.

Working together, I am confident that we will be able to help bring the American people a rational regulatory system that works for them, not against them, and that improves our quality of life, promotes our health and safety, and protects the environment, without imposing undue costs or burdens.

Thank you, Mr. Chairman. I am happy to answer your questions.



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

*RGD*

March 29, 1995

MEMORANDUM FOR DESIGNATED AGENCY HEADS  
(SEE ATTACHED DISTRIBUTION LIST)

FROM: Robert G. Damus *RGD*  
General Counsel *by MGR*

SUBJECT: Proposed Executive Memorandum Entitled "Regulatory Reform"

Attached is a proposed Executive memorandum entitled "Regulatory Reform" that was prepared by this office.

On behalf of the Director of the Office of Management and Budget, I would appreciate receiving any comments you may have concerning this proposal. If you have any comments or objections, they should be received no later than close of business Friday, March 31, 1995. Please be advised that agencies that do not respond by the March 31, 1995 deadline will be recorded as not objecting to the proposal.

Comments or inquiries may be submitted by telephone to Mr. Mac Reed of this office (Phone: 395-3563; Fax: 395-7294).

Thank you.

Attachments - Distribution List  
Proposed Executive Memorandum

cc: Alice Rivlin  
Bob Litan  
Gordon Adams  
T.J. Glauthier  
Joe Minarik  
Ken Apfel  
Nancy-Ann Min  
Sally Katzen  
Steve Kelman  
Bill Halter

DISTRIBUTION LIST

Honorable Warren Christopher  
Secretary  
Department of State

Honorable Robert E. Rubin  
Secretary  
Department of the Treasury

Honorable William Perry  
Secretary  
Department of Defense

Honorable Togo West, Jr.  
Secretary of the Army  
Department of the Army

Honorable John Dalton  
Secretary of the Navy  
Department of the Navy

Honorable Sheila Widnall  
Secretary of the Air Force  
Department of the Air Force

Honorable Janet Reno  
United States Attorney General

Honorable Bruce Babbitt  
Secretary  
Department of the Interior

Honorable Richard Rominger  
Acting Secretary  
Department of Agriculture

Honorable Ron Brown  
Secretary  
Department of Commerce

Honorable Robert Reich  
Secretary  
Department of Labor

Honorable Donna E. Shalala  
Secretary  
Department of Health and Human Services

Honorable Henry G. Cisneros  
Secretary  
Department of Housing and Urban Development



Honorable Federico Pena  
Secretary  
Department of Transportation

Honorable Hazel O'Leary  
Secretary  
Department of Energy

Honorable Richard W. Riley  
Secretary  
Department of Education

Honorable Jesse Brown  
Secretary  
Department of Veterans Affairs

Honorable John Catlin  
Chairman  
Architectural and Transportation Barriers  
Compliance Board

Honorable Trudy Peterson  
Acting Archivist of the United States  
National Archives and Records Administration

Honorable Carol M. Browner  
Administrator  
Environmental Protection Agency

Honorable Gilbert Casellas  
Chairman  
Equal Employment Opportunity Commission

Honorable James Lee Witt  
Director  
Federal Emergency Management Agency

Honorable Roger W. Johnson  
Administrator  
General Services Administration

Honorable Daniel S. Goldin  
Administrator  
National Aeronautics and Space Administration

Honorable Neal Lane  
Director  
National Science Foundation

Honorable James B. King  
Director  
Office of Personnel Management

Honorable Stephen Potts  
Director  
Office of Government Ethics

Honorable Martin I. Slate  
Executive Director  
Pension Benefit Guaranty Corporation

Honorable Glen Bower  
Chairman  
Railroad Retirement Board

Honorable Philip Lader  
Administrator  
Small Business Administration

Honorable Carol Rasco  
Assistant to the President for  
Domestic Policy

Honorable Abner Mikva  
Counsel to the President

Honorable John Podesta  
Assistant to the President  
and Staff Secretary

Honorable Jack Quinn  
Chief of Staff to the Vice President

## MEMORANDUM FOR DESIGNATED AGENCY HEADS (SEE ATTACHED LIST)

SUBJECT: Regulatory Reform

On March 16th, I announced that the Administration would implement new policies to cut back on paperwork and increase the flexibility of compliance officials dealing with small business. These governmentwide policies, as well as the specific agency actions I announced, are part of this Administration's continuing commitment to sensible regulatory reform. Together with the actions I directed in my memorandum of March 4, 1995, these steps will help move the government toward a leaner, more flexible, and more efficient approach to regulation.

Actions: This memorandum directs designated agency heads to implement the policies set forth below.

1. Authority to Waive Penalties.

(a) Each agency shall have discretion to modify the punishment for small businesses in certain situations. To the extent permitted by law, the agency may permit a violation to be excused altogether where the violation is corrected within a short period of time appropriate to the violation in question. For those violations that may take longer than the period set by the agency, the agency may waive up to 100% of the punitive fine if the same sum is used to bring the company into compliance. This discretion will apply to first time violations where there has been a good faith effort to comply and where the violation does not involve significant health, safety, or environmental threats, or criminal wrongdoing.

(b) Each agency will implement the policies described in this section on or before June 1, 1995. Each agency shall, by May 1, 1995, submit a plan to the Director of the Office of Management and Budget ("Director") describing the actions it will take to implement the policies in this section. Plans should include information on how notification will be given to front-line workers and small businesses.

2. Cutting Frequency of Reports. Each agency shall reduce by one-half the frequency of the regularly scheduled reports made by members of the public to the agency (from quarterly to biannually, from biannually to annually, etc.), unless the department or agency head determines that such action is not legally permissible; would not adequately protect public health, safety, or the environment; or would be inconsistent with the mission of the agency. The duty to make such determinations shall be non-delegable.

The reductions in reporting frequency directed here shall be reflected in the agency's June 1 submission required by my memorandum of March 4, 1995.

**Application and Scope:** 1. The Director may issue further guidance as necessary to carry out the purposes of this memorandum.

2. This memorandum does not apply to matters related to government taxes, fees, revenues or receipts; nor does it apply to agencies whose principal purpose is the collection, analysis, and dissemination of statistical information.

3. This memorandum is not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees.

4. This memorandum shall be published in the Federal Register.

THE WHITE HOUSE

## LIST OF DESIGNATED AGENCY HEADS

Secretary of State  
Secretary of the Treasury  
Secretary of Defense  
Secretary of the Army  
Secretary of the Navy  
Secretary of the Air Force  
Attorney General  
Secretary of the Interior  
Secretary of Agriculture  
Secretary of Commerce  
Secretary of Labor  
Secretary of Health and Human Services  
Secretary of Housing and Urban Development  
Secretary of Transportation  
Secretary of Energy  
Secretary of Education  
Secretary of Veterans Affairs  
Chairperson, Architectural and Transportation  
Barriers Compliance Board  
Archivist of the United States  
Administrator, Environmental Protection Agency  
Chair, Equal Employment Opportunity Commission  
Director, Federal Emergency Management Agency  
Administrator, General Services Administration  
Administrator, National Aeronautics and Space  
Administration  
Director, National Science Foundation  
Director, Office of Personnel Management  
Director, Office of Government Ethics  
Executive Director, Pension Benefit Guaranty Corporation  
Chair, Railroad Retirement Board  
Administrator, Small Business Administration

**DRAFT**

3:30

4-6-95

MEMORANDUM FOR DESIGNATED DEPARTMENT AND AGENCY HEADS  
(SEE ATTACHED LIST)

SUBJECT: Regulatory Reform - Waiver of Penalties and  
Reduction of Reports

On March 16th, I announced that the Administration would implement new policies to give compliance officials more flexibility in dealing with small business and to cut back on paperwork. These governmentwide policies, as well as the specific agency actions I announced, are part of this Administration's continuing commitment to sensible regulatory reform. With your help and cooperation, we hope to move the government toward a more flexible, effective, and user friendly approach to regulation.

A. **Actions:** This memorandum directs the designated department and agency heads to implement the policies set forth below.

1. Authority to Waive Penalties.

(a) To the extent permitted by law, each agency shall use its discretion to modify the penalties for small businesses in the following situations. Agencies shall exercise their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within a time appropriate to the violation in question. For those violations that may take longer to correct than the period set by the agency, the agency may waive up to 100 percent of the penalties if the amounts waived are used to bring the company into compliance. The provisions in paragraph 1(a) of this memorandum shall apply only to [first-time violations] where there has been a good faith effort to comply and the violation does not involve criminal wrongdoing or significant threat to health, safety, or the environment.

(b) Each agency shall, by June 1, 1995, submit a plan to the Director of the Office of Management and Budget ("Director") describing the actions it will take to implement the policies in paragraph 1(a) of this memorandum. The plan shall provide that the agency will implement the policies described in paragraph 1(a) of this memorandum on or before July 1, 1995. Plans should include information on how notification will be given to front-line workers and small businesses.

## 2. Cutting Frequency of Reports.

(a) Each agency shall reduce by one-half the frequency of the regularly-scheduled reports that the public is required, by rule or by policy, to provide to the government (from quarterly to semiannually, from semiannually to annually, etc.), unless the department or agency head determines that such action is not legally permissible; would not adequately protect health, safety, or the environment; would be inconsistent with achieving regulatory flexibility or reducing regulatory burdens; or would impede the effective administration of the agency's program. The duty to make such determinations shall be non-delegable.

(b) Each agency shall, by June 1, 1995, submit a plan to the Director of OMB describing the actions it will take to implement the policies in this paragraph 2(a), including a copy of any determination that certain reports are excluded.

**B. Application and Scope:** 1. The Director may issue further guidance as necessary to carry out the purposes of this memorandum.

2. This memorandum does not apply to matters related to law enforcement, national security, or foreign affairs, the importation or exportation of prohibited or restricted items, government taxes, duties, fees, revenues or receipts; nor does it apply to agencies (or components thereof) whose principal purpose is the collection, analysis, and dissemination of statistical information.

3. This memorandum is not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees.

4. This memorandum shall be published in the Federal Register.

THE WHITE HOUSE,

LIST OF DESIGNATED DEPARTMENT AND AGENCY HEADS

Secretary of State  
Secretary of the Treasury  
Secretary of Defense  
Secretary of the Army  
Secretary of the Navy  
Secretary of the Air Force  
Attorney General  
Secretary of the Interior  
Secretary of Agriculture  
Secretary of Commerce  
Secretary of Labor  
Secretary of Health and Human Services  
Secretary of Housing and Urban Development  
Secretary of Transportation  
Secretary of Energy  
Secretary of Education  
Secretary of Veterans Affairs  
Chairperson, Architectural and Transportation  
Barriers Compliance Board  
Archivist of the United States  
Administrator, Environmental Protection Agency  
Director, Federal Emergency Management Agency  
Administrator, General Services Administration  
Administrator, National Aeronautics and Space  
Administration  
Director, National Science Foundation  
Director, Office of Personnel Management  
Executive Director, Pension Benefit Guaranty Corporation  
Chair, Railroad Retirement Board  
Administrator, Small Business Administration

E X E C U T I V E   O F F I C E   O F   T H E   P R E S I D E N T

06-Apr-1995 03:27pm

TO:            Abner J. Mikva

FROM:          Sally Katzen  
                Office of Mgmt and Budget, OIRA

SUBJECT:      Draft Presidential Memo re March 16 Speech

I have asked my assistant to set up a meeting between you, Elaine, and me (and perhaps one or two others) to discuss the above topic. In short, the draft memo that went out for agency review and comment has been revised, and I want to raise a couple of issues to you (and would welcome any additional comments that you might want to offer). Phyllis will be in touch with your office to set up the meeting, and Mac Reed will be delivering a copy of the draft to you this afternoon. Thanks.

April 28, 1995

MEMORANDUM

TO: Regulatory Working Group

FROM: Sally Katzen

SUBJECT: Science and Technology Materials

In preparation for the upcoming session with the Vice President on the topic of Science and Technology (currently scheduled for May 9), we are circulating the attached two drafts. These drafts reflect very thoughtful work by the OSTP team over the past several months. We understand that some of you have been active participants in the development of these papers; others of you may have a passing interest in at least some of the topics addressed; and still others may have no interest at all.

If you have comments on these materials, please relay them to Julie Swisshelm in Dr. Gibbons' office (456-6041, OEOB Room 423, Internet [SWISS@OSTP.EOP.GOV](mailto:SWISS@OSTP.EOP.GOV)) -- by close of business, Wednesday, May 3. If you offer comments, you will be invited to the agenda-setting meeting (which will take place in advance of the meeting with the Vice President). Even if you have no comments on these drafts, you may be included in the agenda-setting meeting by contacting Phyllis Kaiser-Dark of my office (202-395-4852). Thank you.

**RECOMMENDED APPROACHES TO REGULATORY AND  
RELATED ISSUES IN  
SCIENCE AND TECHNOLOGY**

**Draft  
April 28, 1995**

draft -- April 28, 1995

RECOMMENDED APPROACHES TO REGULATORY AND  
RELATED ISSUES IN  
SCIENCE AND TECHNOLOGY

National Performance Review Phase 2

The Office of Science and Technology Policy has played an important support role in coordinating the reinvention efforts of the Federal agencies with significant science and technology portfolios. These agency initiatives have met with considerable enthusiasm, and expectations are high that they will spell success in making the Federal S&T enterprise more efficient, more effective, and more responsive to National needs.

There is a small subset of issues, however, that is not agency-specific. These issues have broad applicability across the research and development spectrum, and they are the focus of the recommendations laid out in this document.

The attached two documents are a briefing agenda and a background document with additional programmatic detail. A table of contents is included with the background document.

The issues include **simplifying approval of the products of biotechnology**, particularly useful drugs; **streamlining procurement and private-sector funding processes**; and **streamlining the university research process** to make sure that each Federal dollar invested yields maximum returns both in research and in the time and energy of researchers. This latter category also emphasizes harnessing the **national information revolution** to reduce the burden of paperwork and free up researcher time for teaching, writing, research, and scholarly activity; the attached report addresses only a small part of this topic, which is to be the subject of a separate briefing at a later date.

There is one outstanding issue that we had intended to include in this document: **reform of export regulations**. Achieving consensus on this issue has proved even more difficult than it seemed at the outset, but -- working with NSC and CEA -- we believe that progress is being made within the agencies to resolve outstanding differences. We hope to be able to present this information in a separate briefing or as part of our upcoming briefing, as appropriate.

The attached two documents are a briefing agenda and a background document with additional programmatic detail. A table of contents is included with the background document.

## **Briefing for Regulation of Science and Technology**

**Scope:** Regulatory issues which affect business incentives to conduct R&D or the productivity of business, university, and federal research and development, and which have not been covered in other regulatory review sessions.

The proposals discussed here include (1) reform efforts already underway that we should highlight as a part of our regulatory reform program, (2) reforms that can be accomplished under existing authority, and (3) reforms that require new legislation.

### **Reform Efforts Underway**

- I. Conduct of Research and Development
  - A. Streamlining the University Research Process
    - 1. Reform the Treatment of Research Costs
    - 2. A System for Continuous Quality Improvement
- II. Federal Leadership in Coordinating Federal, State, and Local Regulatory Activities
- III. Biotechnology
  - A. Simplify Approval of Biotechnology Drugs and Biologics

### **Outstanding Issues**

- I. Conduct of Research and Development
  - A. Streamlining the University Research Process
    - 1. Standardizing the Grant Process
    - 2. Electronic Communications in the Grants Process
    - 3. Easing the Burden of Laboratory Waste Disposal
  - B. Streamline the Private Sector Research Funding Process
  - C. Expand "Other Transactions" Authority for Certain Types of Procurement

- D. Extend Non-Disclosure Protection to Additional Technology Partnerships
- E. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations

## II. Biotechnology

- A. Facilitate Bioremediation Field Trials and Commercialization

## III. Export Regulations

- A. Create an Acceptable and Effective Commodity Jurisdiction Dispute Resolution Procedure *(not included in this document)*

## **I. Conduct of Research and Development**

### **A. Streamline the University Research Process**

#### **1. Streamline the Grant Process**

Differences in practice and policy across Federal agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency with which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine federal agencies, is designed to improve the management of federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process.

#### **Recommendation**

Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all federal agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.

These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

#### **Pros**

- Uniform policies and procedures for the administration of federal research project grants free faculty from paperwork and allow them to spend more time on research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these streamlined procedures saved more than 5 days annually per investigator, permitting over 50 additional person-years of scholarly activity in this sampling. No cases of mismanagement have been attributable to the implementation of the FDP terms and conditions at 50 institutions by 9 federal agencies since the inception of FDP in 1988. Grants offi-

cers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) concur with these recommendations.

**Cons**

- Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity. The major research-sponsoring agencies, including the NIH and the NSF, are largely in compliance with these procedures now.

## **2. Use Electronic Communication to Make the Grants Process More Efficient**

A number of federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. Agencies will need to establish common data requirements for their grants submissions and reporting; commit adequate resources and effort to develop, pilot, and adopt a common electronic standard; and ensure that sufficient technological options are available to institutions to allow some flexibility in selecting the approaches that are most useful and cost effective to them.

NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monuments high) and that 2.4 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data (i.e., civil rights, drug-free workplace, non-delinquency on Federal debt, etc.).

### **Recommendations**

Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.

Direct agencies to develop and demonstrate electronic commerce systems for the administration of federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information.

Direct OMB, working with the FDP and the Federal Business Practices Working Group, to determine, test and implement the best means of establishing electronic access to profiles of recipients receiving federal financial assistance.

### **Pros**

- These recommendations would greatly simplify the administration of grants.
- NSF has begun a project to re-engineer and automate all processes related to grant proposals, awards and related business practices. NSF and NIH have developed client/serve database systems to permit electronic communication with grantees and grantee organizations. Both of these systems utilize the Internet, enabling grantees using any computer type to access the database to enter or modify data.

**Cons**

- Protocols and standards for electronic submission, processing and reporting of proposals are in an early stage of development and have numerous "kinks" that need to be resolved.

### 3. Ease the Burden of Laboratory Waste Disposal

Regulatory requirements unnecessarily drive up the costs incurred by government, university, and industrial laboratories when handling hazardous wastes during research and testing. That is because the applicable regulations, which focus on large volume industrial processes such as chemical manufacturing, are unwieldy when applied to research-testing procedures, which characteristically involve only tiny volumes of chemicals. One-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could yield increased work-place safety and enhanced environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

For research-intensive universities, expenditures associated with handling hazardous and low level radioactive laboratory waste can account for a significant fraction (about 5%) of total project costs and, in many institutions, are the fastest growing component of overhead.

#### Recommendations

*Short Term.* Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste. To achieve effective waste handling, laboratories need only a small fraction of the authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified locations.

*Long Term.* Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes. In addition to encouraging reforms within existing statutes and regulations, the forum would seek to foster increased reliance on performance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

#### Pros

- Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D.
- Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.
- Essentially no down-side risks.

**Cons**

- Would require the EPA to develop an additional set of rules and forms for small volume facilities.

## **B. Streamline the Private Sector Research Funding Process**

### CRADAs

Much research with industry partners is accomplished through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry in areas consistent with laboratory missions. These CRADAs are used extensively by the federal labs and by many different agencies.

Currently, agencies use a variety of different forms of agreements, include a variety of provisions in their CRADAs. CRADAs often do not have a constant format even within the same agency. In addition, projects involving several agencies often must require that the industry partner deal with all the agencies' various procedures and agreements.

While certain differences are required by statute, many are simply a function of custom and can be streamlined or eliminated. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

#### **Recommendations**

The following recommendations were developed in consultation with NASA, DOE, DOC, and ARPA, which support these recommendations. Other agencies are not affected. The recommendations do not involve legislative change.

**The affected agencies should be directed to begin efforts to ensure, to the extent consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs that are consistent within each agency and as similar as possible across agency lines. The inherent tensions between standardization and flexibility in use will dictate innovative solutions, such as modular CRADA agreements. The Partnership for a New Generation of Vehicles (PNGV) can be cited as a demonstration project that is underway in this area. All participating agencies in that project have reviewed and conformed their CRADA documents to the extent possible for use in that project.**

**If, as is likely, it is not possible to completely standardize practices across agency lines, the affected agencies should be directed to consider the possibility in multi-agency projects of assigning a lead agency to manage the agreement. This would provide a basis for a single approach to negotiation and processing. Statutory considerations that are agency**

specific can be noted in the multi-party agreements without the elements common to all the agencies having to be negotiated afresh for each agency. The lead agency will act as a single point of contact for dealing with the industry partner. This will minimize the multiplicity of effort required of industry.

## **B. Streamline the Private Sector Research Funding Process (continued)**

### Other Research Agreements

With respect to research agreements other than CRADAs, there is a similar problem of inconsistency within agencies and across agency lines, as well as substantive requirements that pose unnecessary barriers to research with the private sector. No pilot work has been done to determine the extent to which these inconsistencies or barriers can be eliminated within current statutory requirements.

Should the agencies be given expanded "other transactions" authority (see next section), all such barriers should be eliminated, although work may remain to be done to make the form of agreements more uniform across agency lines. Prior to enactment of such legislation, the agencies should begin the process of identifying any such barriers which are not required by statute and working toward their removal.

### **Recommendations**

**The PNGV, an existing, interagency R&D effort with the private sector, should be designated as a reinvention laboratory in this area of research agreements.** Agencies involved in PNGV should be directed to (1) review their existing statutory authority to determine the degree of flexibility available to them in negotiating research agreements, particularly in the areas of cost accounting, intellectual property, and multi-party "partnership" arrangements; (2) recommend any necessary changes in policy or statute in order to allow them to streamline the negotiation of R&D agreements; and (3) identify inconsistencies in current practices or requirements among those agencies and the basis for those differences.

The PNGV reinvention laboratory should be directed to report its findings to all agencies involved in research agreements with recommendations for improvement in agency practices.

### **Pros**

The inefficiencies in the current process affect the federal agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies ability to effectively work with industry and leverage that investment for U.S. economic and social benefit.

### **Cons**

Agencies currently control their own procedures and have different statutory constraints. Changes that move toward uniformity are difficult to implement without strong interagency consensus (which has to date been hard to achieve).

- In addition, any effort to give one agency the lead in multi agency projects must be careful to maintain agencies' compliance with the requirements of the Economy Act.
- If consistency is emphasized above all other goals it can lead to acceptance of the "lowest common denominator." Care must be taken to preserve agencies' abilities to seek creative solutions.

### **C. Expand "Other Transactions" Authority for Certain Types of Procurement**

*(Note: this issue is still under discussion among SBA and affected agencies)*

The National Performance Review recommended that heads of civilian agencies be granted authority similar to that provided the Department of Defense in 10 U.S.C. 2371, so-called "other transactions" authority. This expansion of "other transactions" authority would be limited to agreements for research and development, and would not extend to procurement of goods and services. "Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work, and it replaces standard procurement requirements with considerable flexibility to the project managers to craft a contract that contains only those provisions necessary to the particular project, and to revise the working arrangement as research projects evolve. It would eliminate, for example, rigid mandatory intellectual property requirements and use of government accounting principles.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects are deterred from engaging in government research programs because of the inflexible accounting requirements and agreement provisions. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. In one case, DOE had to go through ARPA at DOD to fund a cost-shared demonstration project with six major chemical companies. This project could lead to significant savings in clean up costs, but without "other transactions" authority DOE was unable to negotiate a workable agreement with multiple parties.

#### **Recommendation**

The statutory change recommended by the National Performance Review, to extend "other transactions authority" to civilian research agencies for use in negotiating research and development agreements, should be pursued. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure public understanding and appropriate oversight of the increased discretion to be provided to agency managers.

#### **Pros**

- It is appropriate for R&D work, where the project evolves significantly over its life time, in contrast to standard procurement of goods and services.
- It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations.

#### **Cons**

- Eliminating the requirements for compliance with standard procurement regulations in these projects opens these projects to particular scrutiny and the potential for criticism about mismanagement.
- Expansion of this authority will likely require additional employee training and oversight to ensure that the agencies use this authority only for R&D work, and do not extend its use to procurement of goods and services in an attempt to avoid procurement requirements generally.

#### **D. Extend Non-Disclosure Protection to All DOE Federal Technology Partnerships**

There are several statutes that provide for the protection from disclosure, including disclosure under the FOIA, for a period of up to 5 years, of information produced under DOE's collaborative agreements for research, development and demonstration with industrial partners (e.g., the Energy Policy Act of 1992 [12 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [5 U.S.C. 3701], the Department of Interior Appropriations [P.L. 102-381], and the Metals Initiative legislation [P.L. 100-680 and 5 U.S.C. 5101]). The language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statutes do not apply to the entire spectrum of agreements in which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with federal agencies. This inconsistency of statutory authority does not appear to be a problem for agencies other than DOE.

#### **Recommendation**

Seek a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under all federal research development and demonstration agreements in all agencies from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date. However, it should be made clear that protection from disclosure does not apply to the research agreement itself, and that absent extraordinary circumstances information on the nature of the agreement will be publicly available.

#### **Pros**

- Would provide consistent treatment of all DOE's Federal partners for all research, development and demonstration agreements and address a significant concern of industry about their ability to protect commercially valuable information developed as partners with the government.
- Since the protection under the Energy Policy Act is limited to 5 years, federal R&D efforts would afterwards be made public allowing others to benefit by taking those results (obtained in part with taxpayer dollars) and build on them.

#### **Cons**

- The Atomic Energy Act of 1954, section 31d states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as otherwise provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly

available. The extension of current non-disclosure provisions to additional research may be criticized on those grounds, with the claim that a few preferred contractors are allowed to tie up research funded with taxpayer support for a period of time long enough to obtain all reasonable commercial potential from that research.

There may be some increased administrative burden involved in protecting additional information from disclosure.

### **E. Specific Example of Targeted Reform: Galvin Commission Recommendations**

As part of the regulatory review, we have identified one additional specific area in which administrative reform would be well-received by the affected communities. DOE issues its own orders to laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies such as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE. The Galvin Commission report clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives, and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Galvin Report. Given the intense budget pressures DOE is under, we recommend that attention be directed toward achieving the large savings and increased efficiency achievable by reducing the excesses identified in the Galvin Report.

#### **Recommendation**

Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising their Directive system. Since March 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 103 of the remaining orders to 42 including 24 orders considered to be the most burdensome by field offices and contractors. This accelerated effort will be completed by July 31, 1995. This will lead to a reduction in contractor requirements and overhead dollars. Orders that merely repeat external regulatory requirements are planned to be eliminated with the understanding that these external requirements must be followed. Any new orders that are developed (or revisions to existing orders) are to include statements of resource impact and justification for issuance. DOE should be directed to complete this process with timelines and deliverables. At a minimum, DOE Orders should be done away with in cases where other federal agency regulations apply. In otherwise unregulated areas, the process should require that permits only those new orders deemed essential to be promulgated. This should lead to a significant reduction in the Federal work force and allow the labs to reduce overhead and devote more of their resources to R&D.

#### **Pros**

- Removes what is generally recognized as excessive and costly oversight
- Responsive to findings of a prestigious review committee

**Cons**

- The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort
- Some Orders are required to fulfill Congressional requirements of DOE's oversight responsibility
- The labs are more interested in carrying out their missions than adhering to regulations hence strenuous oversight is required
- This level of control is necessary to protect the public interest

## **II. Biotechnology**

### **A. Facilitate Bioremediation Field Trials and Commercialization**

There presently exists a reluctance to employ bioremediation in the U.S., largely because it is perceived as unproved technology, regulatory hurdles discourage application, and the purveyors of conventional technology control the market. This reluctance will diminish substantially if large scale trials can be easily established to demonstrate efficacy. This proposal recommends a plan that would facilitate a scientifically objective evaluation of bioremediation as a predictable, safe, and cost effective clean-up option.

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from the Resource Conservation and Recovery Act (RCRA) and its regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1994, they are still not conducive to long-term research. There needs to be a mechanism for expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms comes under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply to research applications on secure federal land. Accordingly, dedicated federal field sites that include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure sites that also have access to appropriate analytical instrumentation include Oak Ridge National Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

#### **Recommendations**

Dedicate one or more secure Federal field sites to coordinated, long-term research to underpin effective bioremediation of contaminated surface and subsurface environments.

Develop minimal state and Federal regulations to govern such restricted site fields trials.

#### **Pros**

- Will accelerate the development of new technology to clean up the environment
- Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

**Cons**

- Will require EPA to develop a new, less stringent clearance for these test sites
- Will create some controversy among environmental public interest groups if not handled properly.

## Regulation of Science and Technology

### Scope

This group focuses on regulatory issues which affect business incentives to conduct R&D or the productivity of business, university, and federal research and development.

The administration has gone to great lengths to work with businesses, universities, and other organizations in structuring its science and technology policy. Concerns about federal regulation are always a major theme. While some concerns target the purposes of the regulation, many center on blizzards of paperwork and record keeping, as well as on confusion, contradictions, delays, and outright rudeness in the way the regulations are administered. While many of these concerns are chronic in nature, there are good reasons to take a new look.

- The rapid rate of technical change in many key industries often means that competitive advantage grows out of moving quickly to the market. This makes it essential that regulatory decisions be fast and efficient without compromising the goal of the regulations, the quality of the decisions, or public safety. There will always be a tension between the need for public scrutiny and the need for speed. But clearly the need for regulatory efficiency has grown.
- The Federal government supports over 40% of all U.S. research and development and two thirds of its fundamental research. The skill with which federal research funds are managed is therefore critical to the health of the entire U.S. R&D enterprise. The Clinton Administration has placed heavy emphasis on research conducted in close partnership with businesses. The technology supported in these partnerships can lead to profitable commercial products for the private firms while supporting the mission objectives of the federal agencies. This relationship has worked well, but it has also highlighted flaws in federal research management that can be minimized through regulatory reform.

Most of the concerns heard from business and universities focus on environmental, OSHA, FDA, financial, or other regulatory issues covered by other groups in the Vice President's regulatory task force. Our purpose here is to take the broad themes developed in

the task force as a whole and apply them to a set of issues that have not been extensively covered elsewhere.

As a result, the discussion that follows focuses in three areas:

1. Increasing the effectiveness and efficiency with which the federal government funds research and development in universities and industry.
2. Using federal leadership to encourage greater coordination between state, local, and federal regulators.
3. Biotechnology

## Contents

### I. Conduct of Research and Development

#### A. Streamlining the University Research Process

1. Reform the Treatment of Research Costs
2. Standardizing the Grant Process
3. Electronic Communications in the Grants Process
4. Easing the Burden of Laboratory Waste Disposal
5. A System for Continuous Quality Improvement

#### B. Streamline the Private Sector Research Funding Process

#### C. Improve Treatment of Intellectual Property

#### D. Expand "Other Transactions" Authority for Certain Types of Procurement

#### E. Extend Non-Disclosure Protection to Additional Technology Partnerships

#### F. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations

### II. Federal Leadership in Coordinating Federal, State, and Local Regulatory Activities

### III. Biotechnology

#### A. Simplify Approval of Biotechnology Drugs and Biologics

**B. Facilitate Bioremediation Field Trials and Commercialization**

## **I. CONDUCT OF RESEARCH AND DEVELOPMENT**

The proposals discussed here include (1) reform efforts already underway that we should highlight as a part of our regulatory reform program, (2) milestones for reforms that can be accomplished under existing authority, and (3) reforms that require new legislation -- most of which is already included in the procurement reform legislation.

### **A. Streamline the University Research Process**

#### **1. Reform the Treatment of Research Costs (A21)**

The cost reimbursement system for overhead or "indirect costs" for research grants has been harshly criticized and allegedly provides federal reimbursement that is widely variant and too generous. There are proposals in Congress to cap the rates used by universities to calculate federal reimbursement and use the resulting "savings" for other federal needs. A legislated cap setting an arbitrary limit on rates would repudiate the cost principles stated in OMB Circular A-21, under which the government has negotiated reimbursement rates with individual universities for decades. Such a cap could deny millions of dollars of reimbursement to universities for research facilities built to undertake federally funded research based on long-standing principles and agreements.

We propose to implement a number of revisions to OMB Circular A-21, which were published in the Federal Register on February 6. OMB and OSTP, working in collaboration with federal agencies and universities, and building on prior work, have completed their study of the system and will recommend the following changes.

Develop uniform methods and procedures. Discard past notions of "direct and indirect" costs which were needlessly complicated and poorly understood. Instead, three new categories of costs, all necessary to the conduct of fundamental research, will be used: research activities, research facilities, and research administration. Standardize methods for determining utility costs and eliminate special studies to reduce the variation in the utility portion of overhead rates across universities. Develop a methodology to determine uniform treatment of special services (such as hazardous waste facilities), to ensure that similar activities are treated consistently by universities. Include other new policies for areas such as: useful life for research equipment, consistent federal agency transition policies for university changes from use-allowance to depreciation, appropriate federal policies for interest costs, uniform accounting methodology, make total costs part of competitive award process.

Make use of cost efficiencies. Force down the average rate universities charge for facilities. Tough federal review of facility construction costs, utilization, and operations and maintenance will be imposed to ensure that federal science agencies are paying only for efficient and reasonable use of university research space. Benchmarks would be established by research and construction experts for different classes of facilities -- which could apply to new construction and existing facilities

### **Pros**

These changes would reinvent the system of cost reimbursement in the spirit of the National Performance Review. They would achieve greater uniformity and cost efficiencies while retaining the core principles of negotiated cost reimbursement based on the government-university sharing of actual costs. The necessary stability would be retained to stimulate universities and their governing boards to invest in world class research and education facilities.

The chief alternatives to these revisions, a cap on reimbursement rates (or an across the board cut of reimbursement), would have serious consequences to the excellence and future vitality of U.S. academic science. Universities presently receiving federal reimbursement for their substantial investments in research facilities would suffer immediate and significant decreases in their federal recovery. Variation among research facility rates of institutions reflects real and legitimate differences among institutions -- universities and colleges vary in the utility, maintenance and labor costs based on their location, the age, condition and type of their facilities, and the nature of research and education which they pursue.

### **Con**

Instead of these refinements to an already complex system, a cap on reimbursement rates or a standardized percentage cut of the reimbursement to all institutions could streamline the process and achieve cost savings for the government. However these costs would be shifted to universities, thus continuing the increase in the university share of costs associated with federally funded research. The system could be made simpler by setting some fixed rate for all universities, although, as stated above this would not reflect the differences among institutions.

## **2. Streamline the Grant Process**

Differences in practice and policy across agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency with which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine federal agencies, is designed to improve the management of federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process:

- Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all federal agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.
- These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

#### **Pros**

- Uniform policies and procedures for the administration of federal research project grants free faculty from paperwork and allow them to spend more time on research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these streamlined procedures saved more than 5 days annually per investigator, permitting over 50 additional person-years of scholarly activity in this sampling. No cases of mismanagement have been attributable to the implementation of the FDP terms and conditions at 50 institutions by 9 federal agencies since the inception of FDP in 1988.
- Grants officers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) concur with these recommendations.

#### **Cons**

- Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity. The major research-sponsoring agencies, including the NIH and the NSF, are largely in compliance with these procedures now.

### 3. Use Electronic Communication to Make the Grants Process More Efficient

A number of federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. These demonstrations of approaches show great promise in significantly changing the grants process. Agencies will need to establish common data requirements for their grants submissions and reporting. Also, agencies will need to commit adequate resources and effort to develop, pilot, and adopt a common electronic standard in order that institutions not have to deal with a plethora of agency requirements. Finally they will need to ensure that whatever standards or means they adopt, that sufficient technological options are available to institutions to allow them some flexibility in selecting the approaches that are most useful and cost effective to them.

Current grant applications repetitively require basic information about applicant organizations on every hard copy submitted. This includes routine, descriptive information about the organization (e.g., name, address and type of organization, entity number, and information about organization officials), as well as other information including organizational certifications and representations (e.g., civil rights, drug-free workplace, non-delinquency on Federal debt, etc.). **For example, NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monuments high) and that 2.4 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data.**

#### Recommendations

- Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.
- Direct agencies to develop and demonstrate electronic commerce systems for the administration of federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information. Assessments of the approach most suitable to the greatest number of proposals and recipient institutions should be made under the auspices of the OMB, in coordination with the Federal Business Practices Working Group and the Federal Demonstration Project. Agencies should permit technological options to allow institutions some flexibility in how they submit their proposals and interact

with agencies so as not to require institutions to make costly modifications which they may be unable to afford.

Direct OMB, working with the FDP and the Federal Business Practices Working Group, to determine, test and implement the best means of establishing electronic access to profiles of recipients receiving federal financial assistance. These profiles would include routine descriptive organizational information as well as Federal certification and assurances.

A dual system of electronic and hard copy submissions would have to be maintained during a transition period to aid the institutions and small businesses which may have difficulty in using electronic submission and could not modify their existing technology to comply with federal electronic submission protocols.

#### **Pros**

- These recommendations would greatly simplify the administration of grants. Efforts are already beginning in certain agencies to increase electronic communication in this area.
- DOE has awarded a cooperative agreement for a two year effort to assess the generation, submission and processing of university research grant applications and other research administration processes using EDI X12 standards.
- NSF has begun a project to re-engineer and automate all processes related to grant proposals, awards and related business practices. NSF and NIH have developed client/serve database systems to permit electronic communication with grantees and grantee organizations. Both of these systems utilize the Internet, enabling grantees using any computer type to access the database to enter or modify data.

#### **Cons**

- Protocols and standards for electronic submission, processing and reporting of proposals are in an early stage of development and have numerous "kinks" that need to be resolved.

#### **4. Easing the Burden of Laboratory Waste Disposal**

Regulatory requirements unnecessarily drive up the costs incurred by government, university, and industrial laboratories when handling hazardous wastes during research and testing. That is because the applicable regulations, which focus on large volume industrial processes such as chemical manufacturing, are unwieldy when applied to research-testing proce-

dures, which characteristically involve only tiny volumes of chemicals. Dollars that otherwise would be used to advance science are spent meeting unproductive administrative requirements. Even worse, one-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could yield increased work-place safety and enhanced environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

Expenditures associated with handling hazardous and low level radioactive laboratory waste run into the hundreds of millions of dollars each year. For research-intensive universities, these expenditures can account for a significant fraction (about 5%) of total project costs and, in many institutions, are the fastest growing component of overhead. Waste handling regulations developed specifically for the laboratory could do much to assure a better return on the research investment.

### **Recommendations**

**Short Term.** Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste.

To achieve effective waste handling, laboratories need only a small fraction of the authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified locations. These simple reforms would reduce the volumes of waste handled within and shipped from the organizations with commensurate gains in work-place safety, pollution prevention, and cost savings.

**Long Term.** Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes.

This forum would involve all stakeholder groups, e.g., government, university, or industry labs; national and state regulators; environmental protection advocates; work-place safety advocates; and community representatives. It would be modeled on the series of national laboratory waste workshops conducted last year under the auspices of the Government/University/Industry Research Roundtable of the National Academy of Sciences. In addition to encouraging reforms within existing statutes and regulations ( such as the permit streamlining described above ), the forum would seek to foster increased reliance on perfor-

mance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

**Pros**

- Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D.

- Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.

- Essentially no down-side risks.

**Cons**

- Would require the EPA to develop an additional set of rules and forms for small volume facilities.

**5. A System for Continuous Quality Improvement**

The Federal Demonstration Project has been, and continues to be, an excellent vehicle for identifying and testing time and cost saving suggestions related to academic research. To facilitate the translation of these improvements into practice, an established group of senior Federal officials should be responsible for reviewing FDP results and making recommendations for implementation.

**Recommendation**

- Direct the Committee on Fundamental Science of the NSTC to review FDP demonstration project results and to make recommendations regarding those demonstrations to the Office of Management and Budget, the Office of Science and Technology Policy, and to the heads of all Federal research-sponsoring agencies.

**Pro**

- Anchoring the FDP into the Federal Government through the NSTC will insure the rapid adoption of the results of continuing FDP demonstrations and other streamlining initiatives.

## **B. Streamline the Private Sector Research Funding Process**

### CRADAs

Much research with industry partners is accomplished through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry in areas consistent with laboratory missions. These CRADAs are used extensively by the federal labs and by many different agencies.

Currently, agencies use a variety of different forms of agreements, include a variety of provisions in their CRADAs. CRADAs often do not have a constant format even within the same agency. In addition, projects involving several agencies often must require that the industry partner deal with all the agencies' various procedures and agreements.

While certain differences are required by statute, many are simply a function of custom and can be streamlined or eliminated. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

### **Recommendations**

The following recommendations were developed in consultation with NASA, DOE, DOC, and ARPA, which support these recommendations. Other agencies are not affected. The recommendations do not involve legislative change.

**The affected agencies should be directed to begin efforts to ensure, to the extent consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs that are consistent across agency lines.** The inherent tensions between standardization and flexibility in use will dictate innovative solutions, such as modular CRADA agreements. The Partnership for a New Generation of Vehicles (PNGV) can be cited as a demonstration project that has been completed in this area. All participating agencies in that project have reviewed and conformed their CRADA documents to the extent possible for use in that project. The managers of the PNGV project can be the point of contact for agencies in organizing the interagency work on the larger universe of CRADAs.

If, as is likely, it is not possible to completely standardize agency practice, consideration should be given by the interagency group to the possibility in multi-agency projects to

assigning a lead agency to manage the agreement. This would provide a basis for a single approach to negotiation and processing. Statutory considerations that are agency specific can be noted in the multi-party agreements without the elements common to all the agencies having to be negotiated afresh for each agency. The lead agency will act as a single point of contact for dealing with the industry partner. This will minimize the multiplicity of effort required of industry.

#### Other Research Agreements

With respect to other research agreements, there is a similar problem of inconsistency across agency lines, as well as substantive requirements that pose unnecessary barriers to research with the private sector. (See infra at section I.A with respect to university research). No pilot work has been done to determine the extent to which these inconsistencies or barriers can be eliminated within current statutory requirements.

Should the agencies be given expanded "other transactions" authority (see infra at section I.D), all such barriers should be eliminated, although work may remain to be done to make the form of agreements more uniform across agency lines. Prior to enactment of such legislation the agencies should begin the process of identifying any such barriers which are not required by statute and working toward their removal.

#### **Recommendations**

**The PNGV, an existing, interagency R&D effort with the private sector, should be designated as a reinvention laboratory.** Agencies involved in PNGV should be directed to (1) review their existing statutory authority to determine the degree of flexibility available to them in negotiating research agreements, particularly in the areas of cost accounting, intellectual property, and multi-party "partnership" arrangements; (2) recommend any necessary changes in policy or statute in order to allow them to streamline the negotiation of R&D agreements; and (3) identify inconsistencies in current practices or requirements among those agencies and the basis for those differences.

The PNGV reinvention laboratory should be directed to report its findings to all agencies involved in research agreements with recommendations for improvement in agency practices.

#### **Pros**

The inefficiencies in the current process affect the federal agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies ability to effectively work with industry and leverage that investment for U.S. economic and social benefit.

**Cons**

Agencies currently control their own procedures and have different statutory constraints. Changes that move toward uniformity are difficult to implement without strong interagency consensus (which has to date been hard to achieve).

In addition, any effort to give one agency the lead in multi agency projects must be careful to maintain agencies' compliance with the requirements of the Economy Act.

### **C. Improved Treatment of Intellectual Property**

The inability of the federal government to obtain adequate intellectual property protection for computer software that may ultimately be a basis for private sector technology is currently a barrier to federal labs' work with the private sector in this area, and to the effective leveraging of the federal research effort to strengthen the general economy. Currently, federal laboratories may patent, but not copyright, computer programs written by their employees. Because of this limitation on intellectual property rights, the private sectors' willingness to enter into CRADAs is reduced.

In addition, in particular cases the requirement of the Bayh-Dole Act that the government always retain a government purpose license is viewed by industry as a barrier to government-industry research agreements. While amendment of the Bayh-Dole act is not warranted, expansion of "other transaction" authority (see, infra, at I.D) would give agencies the ability to waive that requirement in the few cases in which that would be appropriate.

#### **Recommendations**

Allowing employees of Federal agencies to copyright computer software developed by them as part of their official duties under, or related to, a CRADA will promote the commercial application of software developed with federal funds and thereby strengthen the economy. Legislation providing this intellectual property protection is included in the "Federal Acquisition Improvement" legislation recently forwarded to the Hill by the Administration (see sections 6101-3). That legislative change should be actively pursued.

The flexibility with respect to intellectual property protection provided to agencies through "other transactions" authority should be pursued legislatively. See, infra, section I.D.

#### **Pros**

The recommended changes for the federal labs will improve the leverage the federal R&D investment provides to the private sector.

Improvements in the efficiency of commercial spin-off of federal research through CRADAs and licensing have traditionally received bipartisan support.

#### **Cons**

Federal licensing of intellectual property is currently insignificant in dollar amounts and economic impact. Improvements are possible, but many problems are inevitable consequences of the agencies' focus on mission research as their first priority and limited funding for patent counsel, filings, etc. Thus, the resulting benefits of any statutory change in this area may be relatively small, although significant to particular industry partners.

Regarding intellectual property protection for Federal software, previous attempts to modify the statutes were not strongly supported by industry. There are varying opinions on whether it is better to keep government software in the public domain, or to protect and license it.

#### **D. Expand "Other Transactions" Authority for Certain Types of Procurement**

The National Performance Review recommended that heads of civilian agencies be granted authority similar to that provided the Department of Defense in 10 U.S.C. 2371, so-called "other transactions" authority. This expansion of "other transactions" authority would be limited to agreements for research and development, and would not extend to procurement of goods and services.

"Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work, and it replaces standard procurement requirements with considerable flexibility to the project managers to craft a contract that contains only those provisions necessary to the particular project, and to revise the working arrangement as research projects evolve. It would eliminate, for example, rigid mandatory intellectual property requirements and use of government accounting principles. In some cases, it also would allow R&D contracts to be let without the use of competitive bidding practices, although DOD's experience with this authority has resulted in their voluntary use of competitive bidding practices in over 90% of their agreements.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects, are deterred from engaging in government research programs because of the inflexible accounting requirements and agreement provisions. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. In one case, DOE had to go through ARPA at DOD to fund a cost-shared demonstration project with six major chemical companies. This project could lead to significant savings in clean up costs, but without "other transactions" authority DOE was unable to negotiate a workable agreement with multiple parties.

This statutory change would greatly increase government flexibility in negotiating and updating agreements with private sector partners for technology R&D. It would allow agencies to make agreements with commercial organizations for applied and basic research projects based on best commercial practices, but with a minimum of administrative burden.

### **Recommendations**

The statutory change recommended by the National Performance Review, to extend "other transactions authority" to civilian research agencies for use in negotiating research and development agreements, should be pursued. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure public understanding and appropriate oversight of the increased discretion to be provided to agency managers.

### **Pros**

Other transactions authority is appropriate for research and development work, where the project evolves significantly over its lifetime, and in contrast to standard procurement of goods and services. It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements.

### **Cons**

Eliminating the requirements for compliance with standard procurement regulations in these projects opens these projects to particular scrutiny by those who may not be supporters of the federal R&D effort, and the potential for criticism about mismanagement. Because of the wide discretion provided to agencies under this authority, these projects must be able to demonstrate that they are administered fairly and in a cost-effective manner and that the flexibility provided is not abused.

Expansion of this authority will likely require additional employee training and oversight to ensure that the agencies use this authority only for R&D work, and do not extend its use to procurement of goods and services in an attempt to avoid procurement requirements generally.

The SBA is concerned that the interests of small business would not be fully protected without existing set-asides and competitive bidding practices. Currently, about 7% of federal R&D spending outside the SBIR program goes to small business. This "other transactions"

authority would NOT alter the SBIR program. In addition, the experience of ARPA in its use of "other transactions" authority has been that all but one of such projects have been competitively bid and the project that was not subject to competition went to a small business. In addition, the flexibility available in negotiating agreements simplifies the process for small business, and makes participation more likely for businesses that are not currently able to deal with the procedural requirements of typical government cost-reimbursed contracts and the required accounting procedures.

#### **E. Extend Non-Disclosure Protection to All DOE Federal Technology Partnerships**

There are several statutes that provide for the protection from disclosure, including disclosure under the FOIA, for a period of up to 5 years, of information produced under DOE's collaborative agreements for research, development and demonstration with industrial partners (e.g., the Energy Policy Act of 1992 [12 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [5 U.S.C. 3701], the Department of Interior Appropriations [P.L. 102-381], and the Metals Initiative legislation [P.L. 100-680 and 5 U.S.C. 5101]). The language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statutes do not apply to the entire spectrum of agreements in which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with federal agencies. This inconsistency of statutory authority does not appear to be a problem for agencies other than DOE.

#### **Recommendation**

This barrier to research with industry partners could be most effectively addressed by a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under all federal research development and demonstration agreements in all agencies from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date.

#### **Pros**

Would provide consistent treatment of all DOE's Federal partners for all research, development and demonstration agreements and address a significant concern of industry about their ability to protect commercially valuable information developed as partners with the government.

Since the protection under the Energy Policy Act is limited to 5 years, federal R&D efforts would afterwards be made public allowing others to benefit by taking those results (obtained in part with taxpayer dollars) and build on them.

### **Cons**

The Atomic Energy Act of 1954, section 31d states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as otherwise provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly available. The extension of current non-disclosure provisions to additional research may be criticized on those grounds, with the claim that a few preferred contractors are allowed to tie up research funded with taxpayer support for a period of time long enough to obtain all reasonable commercial potential from that research.

There may be some increased administrative burden involved in protecting additional information from disclosure.

## **F. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations**

As part of the regulatory review, we have identified one additional specific area in which administrative reform would be well-received by the affected communities.

DOE issues its own orders to laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies such as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE.

An extensive review of the DOE laboratories has just been completed, chaired by Robert Galvin, Chairman of the Executive Committee of Motorola clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives, and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Galvin Committee Report. Given the intense budget pressures DOE will be under, we recommend that attention be directed toward achieving the large savings and increased efficiency that could be achieved by reducing the excesses identified in the Galvin Report.

### **Recommendation**

Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising their Directive system. Since March 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 103 of the remaining orders to 42 including 24 orders considered to be the most burdensome by our field offices and contractors. This accelerated effort will be completed by July 31, 1995. This will lead to a reduction in contractor requirements and overhead dollars. Orders that merely repeat external regulatory requirements are planned to be eliminated with the understanding that these external requirements must be followed. Any new orders that are developed (or revisions to existing orders) are to include statements of resource impact and justification for issuance. DOE should be directed to complete this process with timelines and deliverables. At a minimum, DOE Orders should be done away with in cases where other federal agency regulations apply. In otherwise unregulated areas, the process should require that permits only those new orders

deemed essential to be promulgated. This should lead to a significant reduction in the Federal work force and allow the labs to reduce overhead and devote more of their resources to R&D.

**Pros**

- Removes what is generally recognized as excessive and costly oversight
- Responsive to findings of a prestigious review committee
- The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort

**Cons**

- Some Orders are required to fulfill Congressional requirements of DOE's oversight responsibility
- The labs are more interested in carrying out their missions than adhering to regulations hence strenuous oversight is required
- This level of control is necessary to protect the public interest

## **II. FEDERAL LEADERSHIP IN COORDINATING FEDERAL, STATE, AND LOCAL REGULATORY ACTIVITIES**

The burden of making regulatory activity operate more effectively rests at least as much on state and local regulators as it does on the federal government. The federal government is in a unique position to provide leadership. Federal opportunities to work with states to establish linked electronic systems were discussed in an earlier section. New communication technologies will permit citizens to have a single point of entry, perhaps specialized to their unique interests, with links to all levels of government.

There are, however, many other areas where federal leadership could work to streamline complex, and occasionally contradictory regulatory actions at all levels of government. The actions needed will vary with each sector. Major actions are already underway in several areas including wage and tax reporting and efforts to coordinate product approval and building codes for the construction industry. We should take credit for those actions, which are well underway.

Specific examples of projects could include:

- Coordinating of state, and federal wage and tax reporting. The interagency Government Information Technology Services group is developing coordinated electronic reporting systems for wages and taxes that will greatly simplify reporting requirements for individuals and businesses
- Coordinating building codes and inspections. NIST and the Department of Energy are facilitating work by state and local building code organizations to provide a system that will simplify regulatory approvals for builders that must work in several jurisdictions and create reciprocity in approvals.
- Developing national standards for building products. NIST and DOE are also facilitating a process by which producers of building components can have technologies inspected and certified in a way that will satisfy state, regional, or national criteria and avoid redundant and expensive inspection and certification. The certifications and standards are unlikely to involve federal regulation but involve non-federal consortia or private inspection labs.
- Coordination of state, local, and federal environmental and zoning requirements. Builders and developers face a maze of requirements, paperwork, and inspections from

many different levels of government. Experiments which could combine all requirements in an integrated system would be of enormous value to the industry.

### **Recommendation**

The State and Federal Task Force should be asked to propose areas where Federal, State, and local regulatory activities could be brought together in a way that simplifies compliance and reporting for specific groups. Agencies with a prime responsibility in the area should be assigned to take the leadership in convening state and local regulatory authorities. A planning meeting involving the lead agency representatives and representatives of non-federal regulatory bodies should be convened to plan specific actions.

#### **Pros**

- The regulatory burdens faced by citizens and businesses can be reduced dramatically only if all levels of government cooperate in a streamlining effort.
- Progress in this area is eagerly solicited by the business community affected.

#### **Cons**

- May be difficult to deliver on schedule given the complexity of working with many different jurisdictions
- Without care, it may appear that the federal government is trying to usurp local functions

### III. BIOTECHNOLOGY

Part of the impetus behind the effort to streamline and revamp Federal regulatory programs is the need to provide a system that encourages rather than stifles innovation and diffusion of newer, more efficient and cleaner technologies. Modern molecular biology offers several examples of how technological advances and increased understanding of biological processes are changing research, development and manufacturing in a variety of industrial sectors. Regulations that were intended to manage risks associated with new chemical entities or physical processes may not provide the optimal framework for newer products and processes based on biological materials. Two examples of areas of difficulty are the Food and Drug Administration and the Environmental Protection Agency.

#### A. Simplify Approval of Biotechnology Drugs and Biologics

The majority of biotechnology products are reviewed by the Center for Biologics Evaluation and Review (CBER), although some are referred to the Center for Drug Development Evaluation and Review (CDER). The two centers operate under different authorizing legislation reflecting their individual historical mandates. This has led to inconsistencies in review and approval procedures that penalized drug manufacturers in certain cases. FDA has recognized this and has proposed a number of suggestions to remove the regulatory burden on CBER applicants and bring their reviews closer to procedures followed by CDER. This is very important in order to offer drug developers and manufacturers the flexibility to capitalize on technological progress as it occurs.

Changes in procedures to encourage the adoption of new methods without sacrificing public health or safety include:

- waiving the need for premarket approval of certain changes in manufacturing processes for biotechnology and traditional drugs,
- allowing the use of pilot facilities to produce drugs for development work, e.g., clinical trials,
- relaxing restrictions on the selection of subcontractors (originally intended to control variability of products made by living systems), and
- eliminating lot certification for insulin and antibiotics and updating quality control procedures for these products.

However, we believe more can be done along similar lines to speed up the approval process, reduce the regulatory burden, and focus agency resources without any decrease in product safety or efficacy.

Specifically, we would recommend as a guiding principle that premarket approval of manufacturing changes be required only in those cases in which the safety and efficacy of the product may be changed as a result of the process change. When the product can be fully documented as safe, effective, and unchanged, such approvals should not be required. The manufacturer would be held responsible for assuring a product that maintains the same safety and efficacy as that produced using the original process.

In addition, manufacturing changes that do require FDA oversight should be allowed to go into effect in a timely fashion unless FDA has reason to object.

**Pro**

The FDA and the Biotechnology Industry Organization support these recommendations.

**Con**

The recommendations cannot be fully accomplished with administrative action alone. Implementation requires changes in the regulations issued under the Food, Drug and Cosmetic Act and the Public Health Service Act.

**B. Facilitate Bioremediation Field Trials and Commercialization**

There presently exists a reluctance to employ bioremediation in the U.S., largely because it is perceived as unproved technology, regulatory hurdles discourage application, and the purveyors of conventional technology control the market. This reluctance will diminish substantially if large scale trials can be easily established to demonstrate efficacy. This proposal recommends a plan that would facilitate a scientifically objective evaluation of bioremediation as a predictable, safe, and cost effective clean-up option.

**Recommendations**

- (1) Dedicate one or more secure Federal field sites to coordinated, long-term research to underpin effective bioremediation of contaminated surface and subsurface environments.
- (2) Develop minimal state and Federal regulations to govern such restricted site fields trials.

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from the Resource Conservation and Recovery Act (RCRA) and its regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1994, they are still not conducive to long-term research. There needs to be a mechanism for expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms comes under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply to research applications on secure federal land.

In order for bioremediation to be successful, additional fundamental information must be obtained through field experimentation. Lacking progress at the field scale, the extensive laboratory knowledge base that now exists cannot be exploited, and successful bioremediation will be largely serendipitous. Major knowledge gaps exist in the areas of delivery and transport of bioremediative agents (both native and genetically-engineered) within a contaminated site; biological fate (i.e., ecology, physiology, genetics) of the bioremediative agents, once they are introduced; availability of waste chemicals (including mixed wastes) to microbial attack, interactions between multiple chemical compounds and bioremediative agents in mixed-waste sites; and process monitoring and validation. These field knowledge gaps - which are bottlenecks to increased use of bioremediation - can be removed or minimized through coordinated iterative field research in the critical disciplines of microbial ecology, physiology, and genetics; geohydrology and geochemistry; and ecotoxicology. As field experimental data are verified, new discoveries can be transferred through engineering to the private sector for commercialization and application. Accordingly, dedicated federal field sites that include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure sites that also have access to appropriate analytical instrumentation include Oak Ridge National Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

**Pros**

- Will accelerate the development of new technology to clean up the environment

- Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

**Cons**

- Will require EPA to develop a new, less stringent clearance for these test sites

Will create some controversy among environmental public interest groups if not handled properly.



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

ADMINISTRATOR  
OFFICE OF  
INFORMATION AND  
REGULATORY AFFAIRS

MEMORANDUM

APR 28 1995

TO: Regulatory Working Group

FROM: Sally Katzen *SK*

SUBJECT: Science and Technology Materials

In preparation for the upcoming session with the Vice President on the topic of Science and Technology (currently scheduled for May 9), we are circulating the attached two drafts. These drafts reflect very thoughtful work by the OSTP team over the past several months. We understand that some of you have been active participants in the development of these papers; others of you may have a passing interest in at least some of the topics addressed; and still others may have no interest at all.

If you have comments on these materials, please relay them to Julie Swisshelm in Dr. Gibbons' office (456-6041, OEOP Room 423, Internet SWISS@OSTP.EOP.GOV) -- by close of business, Wednesday, May 3. If you offer comments, you will be invited to the agenda-setting meeting (which will take place in advance of the meeting with the Vice President). Even if you have no comments on these drafts, you may be included in the agenda-setting meeting by contacting Phyllis Kaiser-Dark of my office (202-395-4852). Thank you.

**RECOMMENDED APPROACHES TO REGULATORY AND  
RELATED ISSUES IN**

**SCIENCE AND TECHNOLOGY**

**Draft  
April 28, 1995**

draft -- April 28, 1995

**RECOMMENDED APPROACHES TO REGULATORY AND  
RELATED ISSUES IN  
SCIENCE AND TECHNOLOGY**

**National Performance Review Phase 2**

The Office of Science and Technology Policy has played an important support role in coordinating the reinvention efforts of the Federal agencies with significant science and technology portfolios. These agency initiatives have met with considerable enthusiasm, and expectations are high that they will spell success in making the Federal S&T enterprise more efficient, more effective, and more responsive to National needs.

There is a small subset of issues, however, that is not agency-specific. These issues have broad applicability across the research and development spectrum, and they are the focus of the recommendations laid out in this document.

The issues include **simplifying approval of the products of biotechnology**, particularly useful drugs; **streamlining procurement and private-sector funding processes**; and **streamlining the university research process** to make sure that each Federal dollar invested yields maximum returns both in research and in the time and energy of researchers. This latter category also emphasizes harnessing the **national information revolution** to reduce the burden of paperwork and free up researcher time for teaching, writing, research, and scholarly activity; the attached report addresses only a small part of this topic, which is to be the subject of a separate briefing at a later date.

There is one outstanding issue that we had intended to include in this document: **reform of export regulations**. Achieving consensus on this issue has proved even more difficult than it seemed at the outset, but -- working with NSC and CEA -- we believe that progress is being made within the agencies to resolve outstanding differences. We hope to be able to present this information in a separate briefing or as part of our upcoming briefing, as appropriate.

The attached two documents are a briefing agenda and a background document with additional programmatic detail. A table of contents is included with the background document.

## **Briefing for Regulation of Science and Technology**

**Scope:** Regulatory issues which affect business incentives to conduct R&D or the productivity of business, university, and federal research and development, and which have not been covered in other regulatory review sessions.

The proposals discussed here include (1) reform efforts already underway that we should highlight as a part of our regulatory reform program, (2) reforms that can be accomplished under existing authority, and (3) reforms that require new legislation.

### **Reform Efforts Underway**

- I. Conduct of Research and Development
  - A. Streamlining the University Research Process
    - 1. Reform the Treatment of Research Costs
    - 2. A System for Continuous Quality Improvement
- II. Federal Leadership in Coordinating Federal, State, and Local Regulatory Activities
- III. Biotechnology
  - A. Simplify Approval of Biotechnology Drugs and Biologics

### **Outstanding Issues**

- I. Conduct of Research and Development
  - A. Streamlining the University Research Process
    - 1. Standardizing the Grant Process
    - 2. Electronic Communications in the Grants Process
    - 3. Easing the Burden of Laboratory Waste Disposal
  - B. Streamline the Private Sector Research Funding Process
  - C. Expand "Other Transactions" Authority for Certain Types of Procurement
  - D. Extend Non-Disclosure Protection to Additional Technology Partnerships
  - E. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations
- II. Biotechnology
  - A. Facilitate Bioremediation Field Trials and Commercialization
- III. Export Regulations
  - A. Create an Acceptable and Effective Commodity Jurisdiction Dispute Resolution Procedure *(not included in this document)*

## I. Conduct of Research and Development

### A. Streamline the University Research Process

#### 1. Streamline the Grant Process

Differences in practice and policy across Federal agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency with which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine federal agencies, is designed to improve the management of federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process.

#### Recommendation

Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all federal agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.

These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

#### Pros

- Uniform policies and procedures for the administration of federal research project grants free faculty from paperwork and allow them to spend more time on research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these streamlined procedures saved more than 5 days annually per investigator, permitting over 50 additional person-years of scholarly activity in this sampling. No cases of mismanagement have been attributable to the implementation of the FDP terms and conditions at 50 institutions by 9 federal agencies since the inception of FDP in 1988. Grants officers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) concur with these recommendations.

#### Cons

- Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity. The major research-sponsoring agencies, including the NIH and the NSF, are largely in compliance with these procedures now.

## **2. Use Electronic Communication to Make the Grants Process More Efficient**

A number of federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. Agencies will need to establish common data requirements for their grants submissions and reporting; commit adequate resources and effort to develop, pilot, and adopt a common electronic standard; and ensure that sufficient technological options are available to institutions to allow some flexibility in selecting the approaches that are most useful and cost effective to them.

NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monuments high) and that 2.4 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data (i.e., civil rights, drug-free workplace, non-delinquency on Federal debt, etc.).

### **Recommendations**

Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.

Direct agencies to develop and demonstrate electronic commerce systems for the administration of federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information.

Direct OMB, working with the FDP and the Federal Business Practices Working Group, to determine, test and implement the best means of establishing electronic access to profiles of recipients receiving federal financial assistance.

### **Pros**

- These recommendations would greatly simplify the administration of grants.
- NSF has begun a project to re-engineer and automate all processes related to grant proposals, awards and related business practices. NSF and NIH have developed client/serve database systems to permit electronic communication with grantees and grantee organizations. Both of these systems utilize the Internet, enabling grantees using any computer type to access the database to enter or modify data.

### **Cons**

- Protocols and standards for electronic submission, processing and reporting of proposals are in an early stage of development and have numerous "kinks" that need to be resolved.

### 3. Ease the Burden of Laboratory Waste Disposal

Regulatory requirements unnecessarily drive up the costs incurred by government, university, and industrial laboratories when handling hazardous wastes during research and testing. That is because the applicable regulations, which focus on large volume industrial processes such as chemical manufacturing, are unwieldy when applied to research-testing procedures, which characteristically involve only tiny volumes of chemicals. One-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could yield increased work-place safety and enhanced environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

For research-intensive universities, expenditures associated with handling hazardous and low level radioactive laboratory waste can account for a significant fraction (about 5%) of total project costs and, in many institutions, are the fastest growing component of overhead.

#### Recommendations

*Short Term.* Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste. To achieve effective waste handling, laboratories need only a small fraction of the authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified locations.

*Long Term.* Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes. In addition to encouraging reforms within existing statutes and regulations, the forum would seek to foster increased reliance on performance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

#### Pros

- Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D.
- Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.
- Essentially no down-side risks.

#### Cons

- Would require the EPA to develop an additional set of rules and forms for small volume facilities.

## **B. Streamline the Private Sector Research Funding Process**

### CRADAs

Much research with industry partners is accomplished through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry in areas consistent with laboratory missions. These CRADAs are used extensively by the federal labs and by many different agencies.

Currently, agencies use a variety of different forms of agreements, include a variety of provisions in their CRADAs. CRADAs often do not have a constant format even within the same agency. In addition, projects involving several agencies often must require that the industry partner deal with all the agencies' various procedures and agreements.

While certain differences are required by statute, many are simply a function of custom and can be streamlined or eliminated. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

#### **Recommendations**

The following recommendations were developed in consultation with NASA, DOE, DOC, and ARPA, which support these recommendations. Other agencies are not affected. The recommendations do not involve legislative change.

The affected agencies should be directed to begin efforts to ensure, to the extent consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs that are consistent within each agency and as similar as possible across agency lines. The inherent tensions between standardization and flexibility in use will dictate innovative solutions, such as modular CRADA agreements. The Partnership for a New Generation of Vehicles (PNGV) can be cited as a demonstration project that is underway in this area. All participating agencies in that project have reviewed and conformed their CRADA documents to the extent possible for use in that project.

If, as is likely, it is not possible to completely standardize practices across agency lines, the affected agencies should be directed to consider the possibility in multi-agency projects of assigning a lead agency to manage the agreement. This would provide a basis for a single approach to negotiation and processing. Statutory considerations that are agency specific can be noted in the multi-party agreements without the elements common to all the agencies having to be negotiated afresh for each agency. The lead agency will act as a single point of contact for dealing with the industry partner. This will minimize the multiplicity of effort required of industry.

## **B. Streamline the Private Sector Research Funding Process (continued)**

### Other Research Agreements

With respect to research agreements other than CRADAs, there is a similar problem of inconsistency within agencies and across agency lines, as well as substantive requirements that pose unnecessary barriers to research with the private sector. No pilot work has been done to determine the extent to which these inconsistencies or barriers can be eliminated within current statutory requirements.

Should the agencies be given expanded "other transactions" authority (see next section), all such barriers should be eliminated, although work may remain to be done to make the form of agreements more uniform across agency lines. Prior to enactment of such legislation, the agencies should begin the process of identifying any such barriers which are not required by statute and working toward their removal.

### **Recommendations**

The PNGV, an existing, interagency R&D effort with the private sector, should be designated as a reinvention laboratory in this area of research agreements. Agencies involved in PNGV should be directed to (1) review their existing statutory authority to determine the degree of flexibility available to them in negotiating research agreements, particularly in the areas of cost accounting, intellectual property, and multi-party "partnership" arrangements; (2) recommend any necessary changes in policy or statute in order to allow them to streamline the negotiation of R&D agreements; and (3) identify inconsistencies in current practices or requirements among those agencies and the basis for those differences.

The PNGV reinvention laboratory should be directed to report its findings to all agencies involved in research agreements with recommendations for improvement in agency practices.

### **Pros**

- The inefficiencies in the current process affect the federal agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies ability to effectively work with industry and leverage that investment for U.S. economic and social benefit.

### **Cons**

- Agencies currently control their own procedures and have different statutory constraints. Changes that move toward uniformity are difficult to implement without strong interagency consensus (which has to date been hard to achieve).
- In addition, any effort to give one agency the lead in multi agency projects must be careful to maintain agencies' compliance with the requirements of the Economy Act.
- If consistency is emphasized above all other goals it can lead to acceptance of the "lowest common denominator." Care must be taken to preserve agencies' abilities to seek creative solutions.

### **C. Expand "Other Transactions" Authority for Certain Types of Procurement**

*(Note: this issue is still under discussion among SBA and affected agencies)*

The National Performance Review recommended that heads of civilian agencies be granted authority similar to that provided the Department of Defense in 10 U.S.C. 2371, so-called "other transactions" authority. This expansion of "other transactions" authority would be limited to agreements for research and development, and would not extend to procurement of goods and services. "Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work, and it replaces standard procurement requirements with considerable flexibility to the project managers to craft a contract that contains only those provisions necessary to the particular project, and to revise the working arrangement as research projects evolve. It would eliminate, for example, rigid mandatory intellectual property requirements and use of government accounting principles.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects are deterred from engaging in government research programs because of the inflexible accounting requirements and agreement provisions. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. In one case, DOE had to go through ARPA at DOD to fund a cost-shared demonstration project with six major chemical companies. This project could lead to significant savings in clean up costs, but without "other transactions" authority DOE was unable to negotiate a workable agreement with multiple parties.

#### **Recommendation**

The statutory change recommended by the National Performance Review, to extend "other transactions authority" to civilian research agencies for use in negotiating research and development agreements, should be pursued. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure public understanding and appropriate oversight of the increased discretion to be provided to agency managers.

#### **Pros**

- It is appropriate for R&D work, where the project evolves significantly over its lifetime, in contrast to standard procurement of goods and services.
- It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations.

#### **Cons**

- Eliminating the requirements for compliance with standard procurement regulations in these projects opens these projects to particular scrutiny and the potential for criticism about mismanagement.
- Expansion of this authority will likely require additional employee training and oversight to ensure that the agencies use this authority only for R&D work, and do not extend its use to procurement of goods and services in an attempt to avoid procurement requirements generally.

#### **D. Extend Non-Disclosure Protection to All DOE Federal Technology Partnerships**

There are several statutes that provide for the protection from disclosure, including disclosure under the FOIA, for a period of up to 5 years, of information produced under DOE's collaborative agreements for research, development and demonstration with industrial partners (e.g., the Energy Policy Act of 1992 [12 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [5 U.S.C. 3701], the Department of Interior Appropriations [P.L. 102-381], and the Metals Initiative legislation [P.L. 100-680 and 5 U.S.C. 5101]). The language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statutes do not apply to the entire spectrum of agreements in which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with federal agencies. This inconsistency of statutory authority does not appear to be a problem for agencies other than DOE.

#### **Recommendation**

Seek a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under all federal research development and demonstration agreements in all agencies from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date. However, it should be made clear that protection from disclosure does not apply to the research agreement itself, and that absent extraordinary circumstances information on the nature of the agreement will be publicly available.

#### **Pros**

- Would provide consistent treatment of all DOE's Federal partners for all research, development and demonstration agreements and address a significant concern of industry about their ability to protect commercially valuable information developed as partners with the government.
- Since the protection under the Energy Policy Act is limited to 5 years, federal R&D efforts would afterwards be made public allowing others to benefit by taking those results (obtained in part with taxpayer dollars) and build on them.

#### **Cons**

- The Atomic Energy Act of 1954, section 31d states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as otherwise provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly available. The extension of current non-disclosure provisions to additional research may be criticized on those grounds, with the claim that a few preferred contractors are allowed to tie up research funded with taxpayer support for a period of time long enough to obtain all reasonable commercial potential from that research.
- There may be some increased administrative burden involved in protecting additional information from disclosure.

### **E. Specific Example of Targeted Reform: Galvin Commission Recommendations**

As part of the regulatory review, we have identified one additional specific area in which administrative reform would be well-received by the affected communities. DOE issues its own orders to laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies such as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE. The Galvin Commission report clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives, and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Galvin Report. Given the intense budget pressures DOE is under, we recommend that attention be directed toward achieving the large savings and increased efficiency achievable by reducing the excesses identified in the Galvin Report.

#### **Recommendation**

Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising their Directive system. Since March 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 103 of the remaining orders to 42 including 24 orders considered to be the most burdensome by field offices and contractors. This accelerated effort will be completed by July 31, 1995. This will lead to a reduction in contractor requirements and overhead dollars. Orders that merely repeat external regulatory requirements are planned to be eliminated with the understanding that these external requirements must be followed. Any new orders that are developed (or revisions to existing orders) are to include statements of resource impact and justification for issuance. DOE should be directed to complete this process with timelines and deliverables. At a minimum, DOE Orders should be done away with in cases where other federal agency regulations apply. In otherwise unregulated areas, the process should require that permits only those new orders deemed essential to be promulgated. This should lead to a significant reduction in the Federal work force and allow the labs to reduce overhead and devote more of their resources to R&D.

#### **Pros**

- Removes what is generally recognized as excessive and costly oversight
- Responsive to findings of a prestigious review committee
- The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort

#### **Cons**

- Some Orders are required to fulfill Congressional requirements of DOE's oversight responsibility
- The labs are more interested in carrying out their missions than adhering to regulations hence strenuous oversight is required
- This level of control is necessary to protect the public interest

## **II. Biotechnology**

### **A. Facilitate Bioremediation Field Trials and Commercialization**

There presently exists a reluctance to employ bioremediation in the U.S., largely because it is perceived as unproved technology, regulatory hurdles discourage application, and the purveyors of conventional technology control the market. This reluctance will diminish substantially if large scale trials can be easily established to demonstrate efficacy. This proposal recommends a plan that would facilitate a scientifically objective evaluation of bioremediation as a predictable, safe, and cost effective clean-up option.

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from the Resource Conservation and Recovery Act (RCRA) and its regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1994, they are still not conducive to long-term research. There needs to be a mechanism for expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms comes under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply to research applications on secure federal land. Accordingly, dedicated federal field sites that include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure sites that also have access to appropriate analytical instrumentation include Oak Ridge National Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

### **Recommendations**

Dedicate one or more secure Federal field sites to coordinated, long-term research to underpin effective bioremediation of contaminated surface and subsurface environments.

Develop minimal state and Federal regulations to govern such restricted site fields trials.

#### **Pros**

- Will accelerate the development of new technology to clean up the environment
- Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

#### **Cons**

- Will require EPA to develop a new, less stringent clearance for these test sites
- Will create some controversy among environmental public interest groups if not handled properly.

## Regulation of Science and Technology

### Scope

This group focuses on regulatory issues which affect business incentives to conduct R&D or the productivity of business, university, and federal research and development.

The administration has gone to great lengths to work with businesses, universities, and other organizations in structuring its science and technology policy. Concerns about federal regulation are always a major theme. While some concerns target the purposes of the regulation, many center on blizzards of paperwork and record keeping, as well as on confusion, contradictions, delays, and outright rudeness in the way the regulations are administered. While many of these concerns are chronic in nature, there are good reasons to take a new look.

- The rapid rate of technical change in many key industries often means that competitive advantage grows out of moving quickly to the market. This makes it essential that regulatory decisions be fast and efficient without compromising the goal of the regulations, the quality of the decisions, or public safety. There will always be a tension between the need for public scrutiny and the need for speed. But clearly the need for regulatory efficiency has grown.
- The Federal government supports over 40% of all U.S. research and development and two thirds of its fundamental research. The skill with which federal research funds are managed is therefore critical to the health of the entire U.S. R&D enterprise. The Clinton Administration has placed heavy emphasis on research conducted in close partnership with businesses. The technology supported in these partnerships can lead to profitable commercial products for the private firms while supporting the mission objectives of the federal agencies. This relationship has worked well, but it has also highlighted flaws in federal research management that can be minimized through regulatory reform.

Most of the concerns heard from business and universities focus on environmental, OSHA, FDA, financial, or other regulatory issues covered by other groups in the Vice President's regulatory task force. Our purpose here is to take the broad themes developed in the task force as a whole and apply them to a set of issues that have not been extensively covered elsewhere.

As a result, the discussion that follows focuses in three areas:

1. Increasing the effectiveness and efficiency with which the federal government funds research and development in universities and industry.
2. Using federal leadership to encourage greater coordination between state, local, and federal regulators.
3. Biotechnology

## **Contents**

- I. Conduct of Research and Development**
  - A. Streamlining the University Research Process**
    - 1. Reform the Treatment of Research Costs**
    - 2. Standardizing the Grant Process**
    - 3. Electronic Communications in the Grants Process**
    - 4. Easing the Burden of Laboratory Waste Disposal**
    - 5. A System for Continuous Quality Improvement**
  - B. Streamline the Private Sector Research Funding Process**
  - C. Improve Treatment of Intellectual Property**
  - D. Expand "Other Transactions" Authority for Certain Types of Procurement**
  - E. Extend Non-Disclosure Protection to Additional Technology Partnerships**
  - F. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations**
- II. Federal Leadership in Coordinating Federal, State, and Local Regulatory Activities**
- III. Biotechnology**
  - A. Simplify Approval of Biotechnology Drugs and Biologics**
  - B. Facilitate Bioremediation Field Trials and Commercialization**

## I. CONDUCT OF RESEARCH AND DEVELOPMENT

The proposals discussed here include (1) reform efforts already underway that we should highlight as a part of our regulatory reform program, (2) milestones for reforms that can be accomplished under existing authority, and (3) reforms that require new legislation -- most of which is already included in the procurement reform legislation.

### A. Streamline the University Research Process

#### 1. Reform the Treatment of Research Costs (A21)

The cost reimbursement system for overhead or "indirect costs" for research grants has been harshly criticized and allegedly provides federal reimbursement that is widely variant and too generous. There are proposals in Congress to cap the rates used by universities to calculate federal reimbursement and use the resulting "savings" for other federal needs. A legislated cap setting an arbitrary limit on rates would repudiate the cost principles stated in OMB Circular A-21, under which the government has negotiated reimbursement rates with individual universities for decades. Such a cap could deny millions of dollars of reimbursement to universities for research facilities built to undertake federally funded research based on long-standing principles and agreements.

We propose to implement a number of revisions to OMB Circular A-21, which were published in the Federal Register on February 6. OMB and OSTP, working in collaboration with federal agencies and universities, and building on prior work, have completed their study of the system and will recommend the following changes.

Develop uniform methods and procedures. Discard past notions of "direct and indirect" costs which were needlessly complicated and poorly understood. Instead, three new categories of costs, all necessary to the conduct of fundamental research, will be used: research activities, research facilities, and research administration. Standardize methods for determining utility costs and eliminate special studies to reduce the variation in the utility portion of overhead rates across universities. Develop a methodology to determine uniform treatment of special services (such as hazardous waste facilities), to ensure that similar activities are treated consistently by universities. Include other new policies for areas such as: useful life for research equipment, consistent federal agency transition policies for university changes from use-allowance to depreciation, appropriate federal policies for interest costs, uniform accounting methodology, make total costs part of competitive award process.

Make use of cost efficiencies. Force down the average rate universities charge for facilities. Tough federal review of facility construction costs, utilization, and operations and maintenance will be imposed to ensure that federal science agencies are paying only for efficient and reasonable use of university research space. Benchmarks would be established by research and construction experts for different classes of facilities -- which could apply to new construction and existing facilities

**Pros**

- These changes would reinvent the system of cost reimbursement in the spirit of the National Performance Review. They would achieve greater uniformity and cost efficiencies while retaining the core principles of negotiated cost reimbursement based on the government-university sharing of actual costs. The necessary stability would be retained to stimulate universities and their governing boards to invest in world class research and education facilities.
- The chief alternatives to these revisions, a cap on reimbursement rates (or an across the board cut of reimbursement), would have serious consequences to the excellence and future vitality of U.S. academic science. Universities presently receiving federal reimbursement for their substantial investments in research facilities would suffer immediate and significant decreases in their federal recovery. Variation among research facility rates of institutions reflects real and legitimate differences among institutions -- universities and colleges vary in the utility, maintenance and labor costs based on their location, the age, condition and type of their facilities, and the nature of research and education which they pursue.

**Con**

- Instead of these refinements to an already complex system, a cap on reimbursement rates or a standardized percentage cut of the reimbursement to all institutions could streamline the process and achieve cost savings for the government. However these costs would be shifted to universities, thus continuing the increase in the university share of costs associated with federally funded research. The system could be made simpler by setting some fixed rate for all universities, although, as stated above this would not reflect the differences among institutions.

**2. Streamline the Grant Process**

Differences in practice and policy across agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency with which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine federal agencies, is designed to improve the management of federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process:

- Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all

federal agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.

- These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

#### Pros

- Uniform policies and procedures for the administration of federal research project grants free faculty from paperwork and allow them to spend more time on research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these streamlined procedures saved more than 5 days annually per investigator, permitting over 50 additional person-years of scholarly activity in this sampling. No cases of mismanagement have been attributable to the implementation of the FDP terms and conditions at 50 institutions by 9 federal agencies since the inception of FDP in 1988.
- Grants officers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) concur with these recommendations.

#### Cons

- Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity. The major research-sponsoring agencies, including the NIH and the NSF, are largely in compliance with these procedures now.

### 3. Use Electronic Communication to Make the Grants Process More Efficient

A number of federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. These demonstrations of approaches show great promise in significantly changing the grants process. Agencies will need to establish common data requirements for their grants submissions and reporting. Also, agencies will need to commit adequate resources and effort to develop, pilot, and adopt a common electronic standard in order that institutions not have to deal with a plethora of agency requirements. Finally they will need to ensure that whatever standards or means they adopt, that sufficient technological options are available to institutions to allow them some flexibility in selecting the approaches that are most useful and cost effective to them.

Current grant applications repetitively require basic information about applicant organizations on every hard copy submitted. This includes routine, descriptive information about the organization (e.g., name, address and type of organization, entity number, and information about organization officials), as well as other information including organizational certifications and representations (e.g., civil rights, drug-free workplace, non-delinquency on

Federal debt, etc.). For example, NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monuments high) and that 2.4 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data.

### Recommendations

- Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.
- Direct agencies to develop and demonstrate electronic commerce systems for the administration of federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information. Assessments of the approach most suitable to the greatest number of proposals and recipient institutions should be made under the auspices of the OMB, in coordination with the Federal Business Practices Working Group and the Federal Demonstration Project. Agencies should permit technological options to allow institutions some flexibility in how they submit their proposals and interact with agencies so as not to require institutions to make costly modifications which they may be unable to afford.
- Direct OMB, working with the FDP and the Federal Business Practices Working Group, to determine, test and implement the best means of establishing electronic access to profiles of recipients receiving federal financial assistance. These profiles would include routine descriptive organizational information as well as Federal certification and assurances.

A dual system of electronic and hard copy submissions would have to be maintained during a transition period to aid the institutions and small businesses which may have difficulty in using electronic submission and could not modify their existing technology to comply with federal electronic submission protocols.

### Pros

- These recommendations would greatly simplify the administration of grants. Efforts are already beginning in certain agencies to increase electronic communication in this area.
- DOE has awarded a cooperative agreement for a two year effort to assess the generation, submission and processing of university research grant applications and other research administration processes using EDI X12 standards.
- NSF has begun a project to re-engineer and automate all processes related to grant proposals, awards and related business practices. NSF and NIH have developed client/serve database systems to permit electronic communication with grantees and grantee organizations. Both of these systems utilize the

Internet, enabling grantees using any computer type to access the database to enter or modify data.

#### Cons

- Protocols and standards for electronic submission, processing and reporting of proposals are in an early stage of development and have numerous "kinks" that need to be resolved.

#### 4. Easing the Burden of Laboratory Waste Disposal

Regulatory requirements unnecessarily drive up the costs incurred by government, university, and industrial laboratories when handling hazardous wastes during research and testing. That is because the applicable regulations, which focus on large volume industrial processes such as chemical manufacturing, are unwieldy when applied to research-testing procedures, which characteristically involve only tiny volumes of chemicals. Dollars that otherwise would be used to advance science are spent meeting unproductive administrative requirements. Even worse, one-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could yield increased work-place safety and enhanced environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

Expenditures associated with handling hazardous and low level radioactive laboratory waste run into the hundreds of millions of dollars each year. For research-intensive universities, these expenditures can account for a significant fraction (about 5%) of total project costs and, in many institutions, are the fastest growing component of overhead. Waste handling regulations developed specifically for the laboratory could do much to assure a better return on the research investment.

#### Recommendations

**Short Term.** Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste.

To achieve effective waste handling, laboratories need only a small fraction of the authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified locations. These simple reforms would reduce the volumes of waste handled within and shipped from the organizations with commensurate gains in work-place safety, pollution prevention, and cost savings.

**Long Term.** Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes.

This forum would involve all stakeholder groups, e.g., government, university, or industry labs; national and state regulators; environmental protection advocates; work-place safety advocates; and community representatives. It would be modeled on the series of national laboratory waste workshops conducted last year under the auspices of the Government/University/Industry Research Roundtable of the National Academy of Sciences. In addition to encouraging reforms within existing statutes and regulations ( such as the permit streamlining described above ), the forum would seek to foster increased reliance on performance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

**Pros**

- Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D.
- Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.
- Essentially no down-side risks.

**Cons**

- Would require the EPA to develop an additional set of rules and forms for small volume facilities.

**5. A System for Continuous Quality Improvement**

The Federal Demonstration Project has been, and continues to be, an excellent vehicle for identifying and testing time and cost saving suggestions related to academic research. To facilitate the translation of these improvements into practice, an established group of senior Federal officials should be responsible for reviewing FDP results and making recommendations for implementation.

**Recommendation**

- Direct the Committee on Fundamental Science of the NSTC to review FDP demonstration project results and to make recommendations regarding those demonstrations to the Office of Management and Budget, the Office of Science and Technology Policy, and to the heads of all Federal research-sponsoring agencies.

**Pro**

- Anchoring the FDP into the Federal Government through the NSTC will insure the rapid adoption of the results of continuing FDP demonstrations and other streamlining initiatives.

## **B. Streamline the Private Sector Research Funding Process**

### CRADAs

Much research with industry partners is accomplished through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry in areas consistent with laboratory missions. These CRADAs are used extensively by the federal labs and by many different agencies.

Currently, agencies use a variety of different forms of agreements, include a variety of provisions in their CRADAs. CRADAs often do not have a constant format even within the same agency. In addition, projects involving several agencies often must require that the industry partner deal with all the agencies' various procedures and agreements.

While certain differences are required by statute, many are simply a function of custom and can be streamlined or eliminated. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

### **Recommendations**

The following recommendations were developed in consultation with NASA, DOE, DOC, and ARPA, which support these recommendations. Other agencies are not affected. The recommendations do not involve legislative change.

**The affected agencies should be directed to begin efforts to ensure, to the extent consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs that are consistent across agency lines. The inherent tensions between standardization and flexibility in use will dictate innovative solutions, such as modular CRADA agreements. The Partnership for a New Generation of Vehicles (PNGV) can be cited as a demonstration project that has been completed in this area. All participating agencies in that project have reviewed and conformed their CRADA documents to the extent possible for use in that project. The managers of the PNGV project can be the point of contact for agencies in organizing the interagency work on the larger universe of CRADAs.**

If, as is likely, it is not possible to completely standardize agency practice, consideration should be given by the interagency group to the possibility in multi-agency projects to assigning a lead agency to manage the agreement. This would provide a basis for a single approach to negotiation and processing. Statutory considerations that are agency specific can be noted in the multi-party agreements without the elements common to all the agencies having to be negotiated afresh for each agency. The lead agency will act as a single point of contact for dealing with the industry partner. This will minimize the multiplicity of effort required of industry.

### Other Research Agreements

With respect to other research agreements, there is a similar problem of inconsistency across agency lines, as well as substantive requirements that pose unnecessary barriers to research with the private sector. (See *infra*, at section I.A with respect to university research). No pilot work has been done to determine the extent to which these inconsistencies or barriers can be eliminated within current statutory requirements.

Should the agencies be given expanded "other transactions" authority (see *infra*, at section I.D), all such barriers should be eliminated, although work may remain to be done to make the form of agreements more uniform across agency lines. Prior to enactment of such legislation the agencies should begin the process of identifying any such barriers which are not required by statute and working toward their removal.

### **Recommendations**

The PNGV, an existing, interagency R&D effort with the private sector, should be designated as a reinvention laboratory. Agencies involved in PNGV should be directed to (1) review their existing statutory authority to determine the degree of flexibility available to them in negotiating research agreements, particularly in the areas of cost accounting, intellectual property, and multi-party "partnership" arrangements; (2) recommend any necessary changes in policy or statute in order to allow them to streamline the negotiation of R&D agreements; and (3) identify inconsistencies in current practices or requirements among those agencies and the basis for those differences.

The PNGV reinvention laboratory should be directed to report its findings to all agencies involved in research agreements with recommendations for improvement in agency practices.

### **Pros**

The inefficiencies in the current process affect the federal agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies ability to effectively work with industry and leverage that investment for U.S. economic and social benefit.

### **Cons**

Agencies currently control their own procedures and have different statutory constraints. Changes that move toward uniformity are difficult to implement without strong interagency consensus (which has to date been hard to achieve).

In addition, any effort to give one agency the lead in multi agency projects must be careful to maintain agencies' compliance with the requirements of the Economy Act.

### C. Improved Treatment of Intellectual Property

The inability of the federal government to obtain adequate intellectual property protection for computer software that may ultimately be a basis for private sector technology is currently a barrier to federal labs' work with the private sector in this area, and to the effective leveraging of the federal research effort to strengthen the general economy. Currently, federal laboratories may patent, but not copyright, computer programs written by their employees. Because of this limitation on intellectual property rights, the private sectors' willingness to enter into CRADAs is reduced.

In addition, in particular cases the requirement of the Bayh-Dole Act that the government always retain a government purpose license is viewed by industry as a barrier to government-industry research agreements. While amendment of the Bayh-Dole act is not warranted, expansion of "other transaction" authority (see, *infra*, at 1.D) would give agencies the ability to waive that requirement in the few cases in which that would be appropriate.

#### Recommendations

Allowing employees of Federal agencies to copyright computer software developed by them as part of their official duties under, or related to, a CRADA will promote the commercial application of software developed with federal funds and thereby strengthen the economy. Legislation providing this intellectual property protection is included in the "Federal Acquisition Improvement" legislation recently forwarded to the Hill by the Administration (see sections 6101-3). That legislative change should be actively pursued.

The flexibility with respect to intellectual property protection provided to agencies through "other transactions" authority should be pursued legislatively. See, *infra*, section I.D.

#### **Pros**

The recommended changes for the federal labs will improve the leverage the federal R&D investment provides to the private sector.

Improvements in the efficiency of commercial spin-off of federal research through CRADAs and licensing have traditionally received bipartisan support.

#### **Cons**

Federal licensing of intellectual property is currently insignificant in dollar amounts and economic impact. Improvements are possible, but many problems are inevitable consequences of the agencies' focus on mission research as their first priority and limited funding for patent counsel, filings, etc. Thus, the resulting benefits of any statutory change in this area may be relatively small, although significant to particular industry partners.

Regarding intellectual property protection for Federal software, previous attempts to modify the statutes were not strongly supported by industry. There are varying opinions on whether it is better to keep government software in the public domain, or to protect and license it.

#### **D. Expand "Other Transactions" Authority for Certain Types of Procurement**

The National Performance Review recommended that heads of civilian agencies be granted authority similar to that provided the Department of Defense in 10 U.S.C. 2371, so-called "other transactions" authority. This expansion of "other transactions" authority would be limited to agreements for research and development, and would not extend to procurement of goods and services.

"Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work, and it replaces standard procurement requirements with considerable flexibility to the project managers to craft a contract that contains only those provisions necessary to the particular project, and to revise the working arrangement as research projects evolve. It would eliminate, for example, rigid mandatory intellectual property requirements and use of government accounting principles. In some cases, it also would allow R&D contracts to be let without the use of competitive bidding practices, although DOD's experience with this authority has resulted in their voluntary use of competitive bidding practices in over 90% of their agreements.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects, are deterred from engaging in government research programs because of the inflexible accounting requirements and agreement provisions. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. In one case, DOE had to go through ARPA at DOD to fund a cost-shared demonstration project with six major chemical companies. This project could lead to significant savings in clean up costs, but without "other transactions" authority DOE was unable to negotiate a workable agreement with multiple parties.

This statutory change would greatly increase government flexibility in negotiating and updating agreements with private sector partners for technology R&D. It would allow agencies to make agreements with commercial organizations for applied and basic research projects based on best commercial practices, but with a minimum of administrative burden.

#### **Recommendations**

The statutory change recommended by the National Performance Review, to extend "other transactions authority" to civilian research agencies for use in negotiating research and development agreements, should be pursued. Any legislative change would

be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure public understanding and appropriate oversight of the increased discretion to be provided to agency managers.

#### **Pros**

Other transactions authority is appropriate for research and development work, where the project evolves significantly over its lifetime, and in contrast to standard procurement of goods and services. It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements.

#### **Cons**

Eliminating the requirements for compliance with standard procurement regulations in these projects opens these projects to particular scrutiny by those who may not be supporters of the federal R&D effort, and the potential for criticism about mismanagement. Because of the wide discretion provided to agencies under this authority, these projects must be able to demonstrate that they are administered fairly and in a cost-effective manner and that the flexibility provided is not abused.

Expansion of this authority will likely require additional employee training and oversight to ensure that the agencies use this authority only for R&D work, and do not extend its use to procurement of goods and services in an attempt to avoid procurement requirements generally.

The SBA is concerned that the interests of small business would not be fully protected without existing set-asides and competitive bidding practices. Currently, about 7% of federal R&D spending outside the SBIR program goes to small business. This "other transactions" authority would NOT alter the SBIR program. In addition, the experience of ARPA in its use of "other transactions" authority has been that all but one of such projects have been competitively bid and the project that was not subject to competition went to a small business. In addition, the flexibility available in negotiating agreements simplifies the process for small business, and makes participation more likely for businesses that are not currently able to deal with the procedural requirements of typical government cost-reimbursed contracts and the required accounting procedures.

#### **E. Extend Non-Disclosure Protection to All DOE Federal Technology Partnerships**

There are several statutes that provide for the protection from disclosure, including disclosure under the FOIA, for a period of up to 5 years, of information produced under DOE's collaborative agreements for research, development and demonstration with industrial partners (e.g., the Energy Policy Act of 1992 [12 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [5 U.S.C. 3701], the Department of Interior Appropriations [P.L. 102-381], and the Metals Initiative legislation [P.L. 100-680 and 5 U.S.C. 5101]). The

language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statutes do not apply to the entire spectrum of agreements in which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with federal agencies. This inconsistency of statutory authority does not appear to be a problem for agencies other than DOE.

### **Recommendation**

**This barrier to research with industry partners could be most effectively addressed by a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under all federal research development and demonstration agreements in all agencies from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date.**

### **Pros**

Would provide consistent treatment of all DOE's Federal partners for all research, development and demonstration agreements and address a significant concern of industry about their ability to protect commercially valuable information developed as partners with the government.

Since the protection under the Energy Policy Act is limited to 5 years, federal R&D efforts would afterwards be made public allowing others to benefit by taking those results (obtained in part with taxpayer dollars) and build on them.

### **Cons**

The Atomic Energy Act of 1954, section 31d states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as otherwise provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly available. The extension of current non-disclosure provisions to additional research may be criticized on those grounds, with the claim that a few preferred contractors are allowed to tie up research funded with taxpayer support for a period of time long enough to obtain all reasonable commercial potential from that research.

There may be some increased administrative burden involved in protecting additional information from disclosure.

## **F. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations**

As part of the regulatory review, we have identified one additional specific area in which administrative reform would be well-received by the affected communities.

DOE issues its own orders to laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies such as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE.

An extensive review of the DOE laboratories has just been completed, chaired by Robert Galvin, Chairman of the Executive Committee of Motorola clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives, and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Galvin Committee Report. Given the intense budget pressures DOE will be under, we recommend that attention be directed toward achieving the large savings and increased efficiency that could be achieved by reducing the excesses identified in the Galvin Report.

### **Recommendation**

Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising their Directive system. Since March 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 103 of the remaining orders to 42 including 24 orders considered to be the most burdensome by our field offices and contractors. This accelerated effort will be completed by July 31, 1995. This will lead to a reduction in contractor requirements and overhead dollars. Orders that merely repeat external regulatory requirements are planned to be eliminated with the understanding that these external requirements must be followed. Any new orders that are developed (or revisions to existing orders) are to include statements of resource impact and justification for issuance. DOE should be directed to complete this process with timelines and deliverables. At a minimum, DOE Orders should be done away with in cases where other federal agency regulations apply. In otherwise unregulated areas, the process should require that permits only those new orders deemed essential to be promulgated. This should lead to a significant reduction in the Federal work force and allow the labs to reduce overhead and devote more of their resources to R&D.

### **Pros**

- Removes what is generally recognized as excessive and costly oversight
- Responsive to findings of a prestigious review committee
- The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort

**Cons**

- Some Orders are required to fulfill Congressional requirements of DOE's oversight responsibility
- The labs are more interested in carrying out their missions than adhering to regulations hence strenuous oversight is required
- This level of control is necessary to protect the public interest

## **II. FEDERAL LEADERSHIP IN COORDINATING FEDERAL, STATE, AND LOCAL REGULATORY ACTIVITIES**

The burden of making regulatory activity operate more effectively rests at least as much on state and local regulators as it does on the federal government. The federal government is in a unique position to provide leadership. Federal opportunities to work with states to establish linked electronic systems were discussed in an earlier section. New communication technologies will permit citizens to have a single point of entry, perhaps specialized to their unique interests, with links to all levels of government.

There are, however, many other areas where federal leadership could work to streamline complex, and occasionally contradictory regulatory actions at all levels of government. The actions needed will vary with each sector. Major actions are already underway in several areas including wage and tax reporting and efforts to coordinate product approval and building codes for the construction industry. We should take credit for those actions, which are well underway.

Specific examples of projects could include:

- Coordinating of state, and federal wage and tax reporting. The interagency Government Information Technology Services group is developing coordinated electronic reporting systems for wages and taxes that will greatly simplify reporting requirements for individuals and businesses
- Coordinating building codes and inspections. NIST and the Department of Energy are facilitating work by state and local building code organizations to provide a system that will simplify regulatory approvals for builders that must work in several jurisdictions and create reciprocity in approvals.
- Developing national standards for building products. NIST and DOE are also facilitating a process by which producers of building components can have technologies inspected and certified in a way that will satisfy state, regional, or national criteria and avoid redundant and expensive inspection and certification. The certifications and standards are unlikely to involve federal regulation but involve non-federal consortia or private inspection labs.
- Coordination of state, local, and federal environmental and zoning requirements. Builders and developers face a maze of requirements, paperwork, and inspections from many different levels of government. Experiments which could combine all requirements in an integrated system would be of enormous value to the industry.

### **Recommendation**

The State and Federal Task Force should be asked to propose areas where Federal, State, and local regulatory activities could be brought together in a way that simplifies

compliance and reporting for specific groups. Agencies with a prime responsibility in the area should be assigned to take the leadership in convening state and local regulatory authorities. A planning meeting involving the lead agency representatives and representatives of non-federal regulatory bodies should be convened to plan specific actions.

**Pros**

- The regulatory burdens faced by citizens and businesses can be reduced dramatically only if all levels of government cooperate in a streamlining effort.
- Progress in this area is eagerly solicited by the business community affected.

**Cons**

- May be difficult to deliver on schedule given the complexity of working with many different jurisdictions
- Without care, it may appear that the federal government is trying to usurp local functions

### **III. BIOTECHNOLOGY**

Part of the impetus behind the effort to streamline and revamp Federal regulatory programs is the need to provide a system that encourages rather than stifles innovation and diffusion of newer, more efficient and cleaner technologies. Modern molecular biology offers several examples of how technological advances and increased understanding of biological processes are changing research, development and manufacturing in a variety of industrial sectors. Regulations that were intended to manage risks associated with new chemical entities or physical processes may not provide the optimal framework for newer products and processes based on biological materials. Two examples of areas of difficulty are the Food and Drug Administration and the Environmental Protection Agency.

#### **A. Simplify Approval of Biotechnology Drugs and Biologics**

The majority of biotechnology products are reviewed by the Center for Biologics Evaluation and Review (CBER), although some are referred to the Center for Drug Development Evaluation and Review (CDER). The two centers operate under different authorizing legislation reflecting their individual historical mandates. This has led to inconsistencies in review and approval procedures that penalized drug manufacturers in certain cases. FDA has recognized this and has proposed a number of suggestions to remove the regulatory burden on CBER applicants and bring their reviews closer to procedures followed by CDER. This is very important in order to offer drug developers and manufacturers the flexibility to capitalize on technological progress as it occurs.

Changes in procedures to encourage the adoption of new methods without sacrificing public health or safety include:

- waiving the need for premarket approval of certain changes in manufacturing processes for biotechnology and traditional drugs,
- allowing the use of pilot facilities to produce drugs for development work, e.g., clinical trials,
- relaxing restrictions on the selection of subcontractors (originally intended to control variability of products made by living systems), and
- eliminating lot certification for insulin and antibiotics and updating quality control procedures for these products.

However, we believe more can be done along similar lines to speed up the approval process, reduce the regulatory burden, and focus agency resources without any decrease in product safety or efficacy.

Specifically, we would recommend as a guiding principle that premarket approval of manufacturing changes be required only in those cases in which the safety and efficacy of the product may be changed as a result of the process change. When the product can be fully documented as safe, effective, and unchanged, such approvals should not be required. The

manufacturer would be held responsible for assuring a product that maintains the same safety and efficacy as that produced using the original process.

In addition, manufacturing changes that do require FDA oversight should be allowed to go into effect in a timely fashion unless FDA has reason to object.

**Pro**

- The FDA and the Biotechnology Industry Organization support these recommendations.

**Con**

- The recommendations cannot be fully accomplished with administrative action alone. Implementation requires changes in the regulations issued under the Food, Drug and Cosmetic Act and the Public Health Service Act.

**B. Facilitate Bioremediation Field Trials and Commercialization**

There presently exists a reluctance to employ bioremediation in the U.S., largely because it is perceived as unproved technology, regulatory hurdles discourage application, and the purveyors of conventional technology control the market. This reluctance will diminish substantially if large scale trials can be easily established to demonstrate efficacy. This proposal recommends a plan that would facilitate a scientifically objective evaluation of bioremediation as a predictable, safe, and cost effective clean-up option.

**Recommendations**

- (1) Dedicate one or more secure Federal field sites to coordinated, long-term research to underpin effective bioremediation of contaminated surface and subsurface environments.
- (2) Develop minimal state and Federal regulations to govern such restricted site fields trials.

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from the Resource Conservation and Recovery Act (RCRA) and its regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1994, they are still not conducive to long-term research. There needs to be a mechanism for expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms comes under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply to research applications on secure federal land.

In order for bioremediation to be successful, additional fundamental information must be obtained through field experimentation. Lacking progress at the field scale, the extensive laboratory knowledge base that now exists cannot be exploited, and successful bioremediation will be largely serendipitous. Major knowledge gaps exist in the areas of delivery and transport of bioremediative agents (both native and genetically-engineered) within a contaminated site; biological fate (i.e., ecology, physiology, genetics) of the bioremediative agents, once they are introduced; availability of waste chemicals (including mixed wastes) to microbial attack, interactions between multiple chemical compounds and bioremediative agents in mixed-waste sites; and process monitoring and validation. These field knowledge gaps - which are bottlenecks to increased use of bioremediation - can be removed or minimized through coordinated iterative field research in the critical disciplines of microbial ecology, physiology, and genetics; geohydrology and geochemistry; and ecotoxicology. As field experimental data are verified, new discoveries can be transferred through engineering to the private sector for commercialization and application. Accordingly, dedicated federal field sites that include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure sites that also have access to appropriate analytical instrumentation include Oak Ridge National Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

**Pros**

- Will accelerate the development of new technology to clean up the environment
- Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

**Cons**

- Will require EPA to develop a new, less stringent clearance for these test sites
- Will create some controversy among environmental public interest groups if not handled properly.