

**REGULATORY REVIEW
HEALTH CARE WORKING GROUP**

<u>Name</u>	<u>Agency</u>	<u>Phone</u>	<u>Fax</u>
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Chris Jennings	DPC	456-5560	456-7431
Kim O'Neill	NEC/DPC	456-5587	456-7431
Judith Riggins	Agriculture	720-4150	690-4437
Mike Taylor	Agriculture	720-7025	690-4437
Jon Baker	CEA	395-1410 <i>5617</i>	395-6853
Eric Wolff	CEA	395-1410	395-6853
Chris Cerf	WH Counsel	456-6229	456-2146
Douglas Letter	WH Counsel	456-7901	456-1647
Bill Schultz	FDA	301-443-2854	
Tom Ault	HHS	410-966-5635	401-966-0594
Chris Bladen	HHS	690-6870	401-7321
Anna Boyd	HHS	690-6111	690-7203
Claudia Cooley	HHS/Office of the Secretary	690-5627	690-7203
Judy Feder	HHS/ASPE	690-7858	690-7383
Harriet Rabb	HHS/OGC	690-7741	690-7998
Jacquelyn White	HHS	690-5627	690-7203
Jerry Stern	DOJ	514-6753	307-0097
Jean Logan	NPR	632-0334	632-0390
Shannah Koss	OMB	395-7318	395-5167
Laurel Illston	OMB	395-7809	
Nelson Reyneri	OSHA	219-9196	219-6064
Mary Lou Keener	VA	273-6660	273-6671
Bob Knisely	OVP/NPR	366-3282	366-3640
		703-757-0292 (Home)	

M E M O R A N D U M

To: Elaine Kamarck
Greg Simon
Sally Katzen

From: Chris Jennings

Date: April 18, 1995

Re: Timeline

cc: Jennifer Klein
Shannah Koss

Attached is the implementation timeline for the regulatory reforms outlined in the recently released FDA report. We can all use this to keep on top of the agency to follow through on the Administration's promised timeframe. I hope you find this useful. Please call me with any questions at 6-5660.

REGO DEVICE PROPOSALS

PROPOSAL	IMPLEMENTATION/TIMELINE
Medical Device Exemptions from Premarket Notification	proposed reclassification and exemption by June 1995
Elimination of the Reference List	immediate review of products on list
Medical Device External Review Pilot Program	pilot program will begin Oct. 1995
Device User Fees	legislation proposed in 1996 budget
Device Exports	legislation; proposed regulation for IDE devices by Oct. 1995
Effectiveness of Devices	published statement by July 1995
Harmonization of Standards	testing: guideline development within 2 years GMPs: guidelines within 2 years

REGO DRUG PROPOSALS

PROPOSAL	IMPLEMENTATION/TIMELINE
Eliminating Many Requirements for FDA Approval of Manufacturing Changes	Drugs: tablet form, guidance document by Dec. 1995 other forms, guidance document by Dec. 1996 Biologics: 1st round guidance document immediately 2nd round proposed regulation by Jan. 1996
New Policy to Permit Use of Small-Scale and Pilot Facilities During Development of Biologics	guidance document by July 1995
Revision of Labeling Requirements for Biological Products	proposed regulation by Oct. 1995
Antibiotic and Insulin Standards and Insulin Certification	legislation
Environmental Assessments for Human Drugs	proposed regulation by Jan. 1995
Drug Exports	legislation
Effectiveness of Drugs	published statement by July 1995
Harmonization	testing: guideline development within 2 years GMPs: guidelines within 2 years animal drugs: guidelines within 3 years

Regulatory Policy Reviews
(As of 1/5/95)

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Abner Mikva			
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Fax changes to Steve Tidrick at 632-0390

Schedule for Health Industry Regulatory Review Initiative

January 12	Reach conclusion on issues to be presented
January 19	Review of presentation, including case studies, description of past regulatory approaches, new vision for future (with specific proposals and discussion of why we rejected other new approaches)
January 24	Additional review of presentation
January 27(?)	Practice presentation for DPC
February 2	Presentation to Vice President

THE WHITE HOUSE
WASHINGTON

January 5, 1995

MEMORANDUM FOR THE VICE PRESIDENT

FROM: CAROL RASCO 

SUBJECT: **Regulatory Reform Initiative**

The purpose of this memorandum is to update on the status of the three DPC-led working groups of your regulatory review initiative. Prior to the Christmas break, I appointed the chairs of the three groups:

1. Education -- Bill Galston, Gaynor McCown
2. Workplace Safety -- Michael Waldman, Michael Schmidt
3. Health Industry Regulation/
Food and Drug Regulation -- Chris Jennings, Jennifer Klein

. The working groups are off to a fast start and the chairs have convened several meetings with the appropriate agency representatives.

Because of the urgency of this initiative, I wanted to provide you with an outline of our proposed presentation from the three working groups. All three groups are planning, within the two hours allotted with you, to do the following:

1. Provide you with two to four major areas of reforms with pros and cons on both bold and moderate options. All three working groups believe it is necessary to focus on a few areas that offer the best chance for regulatory improvement (low-hanging fruit).
2. Each group will try to bring a customer-service perspective to the presentation. For example, the education working group is looking at regulations through the viewpoint of a principal and a college president. The other two working groups will follow a similar approach.
3. Each group will provide case studies of certain regulatory areas to provide a context of real life experiences.
4. Each group will try to focus on why past regulatory choices were made and what implications we can draw from them.

5. Each group will explore a vision of a different future.

Prior to the presentation, we would like to circulate the materials at least 24 hours in advance. In addition, I am planning to have a dry run of the presentations made to me before the meetings with you.

Please advise me if this plan of action meets with your approval.

DECISION

Approve

Discuss Further

Organization of Teams for NPR Phase II

IA. Large Agency Teams Effort
<i>National Security and International Affairs</i> Defense State Intelligence Community
<i>Natural Resources, Energy, and Science</i> Agriculture Environmental Protection Agency Interior National Science Foundation NASA
<i>Human Resources</i> Education Labor Health and Human Services (part) Social Security Administration
<i>Health and Personnel</i> Veterans Affairs Health and Human Services (part)
<i>General Government</i> Commerce Small Business Administration Justice Federal Emergency Management Agency Treasury Postal Service

IB. Small Agency Teams Effort (number of teams to be determined to cover the roughly 120 small agencies). Could group by major cabinet agency or by natural clusters, such as:

- International Affairs (17 agencies)
- Natural Resources (13 agencies)
- Cultural Activities (17 agencies)
- Education (8 agencies)
- Human Resources (13 agencies)
- Business and Trade (8 agencies)
- Financial Services (17 agencies)
- Legal (7 agencies)
- Other (18 agencies)

II. Federalism and Devolution Effort

III. Regulatory Reinvention Effort

IV. Implementation of NPR Phase I

- Streamlining
- Customer Service Standards
- Virtual Department of Business
- Public Service Reform

V. Support: Research and Special Skills Staff

Subsidy Identification Effort

Streamlining Effort

Customer Survey Skills

Privatization Effort

Individual Empowerment Effort

VI. Legislative-Executive Relations - Lorraine Miller

Bev Godwin -
Side-by-side
look at 6 major
works of this
issue.

70 U.S. Rep. C. S. ...



OFFICE OF THE VICE PRESIDENT
WASHINGTON

January 5, 1995

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES
FROM ELAINE KAMARCK, SENIOR POLICY ADVISOR TO THE VICE PRESIDENT
and BOB STONE, PROJECT DIRECTOR, NATIONAL PERFORMANCE REVIEW
SUBJECT: Second Phase of the National Performance Review

The Vice President's memo of January 3 (same subject) started a review to

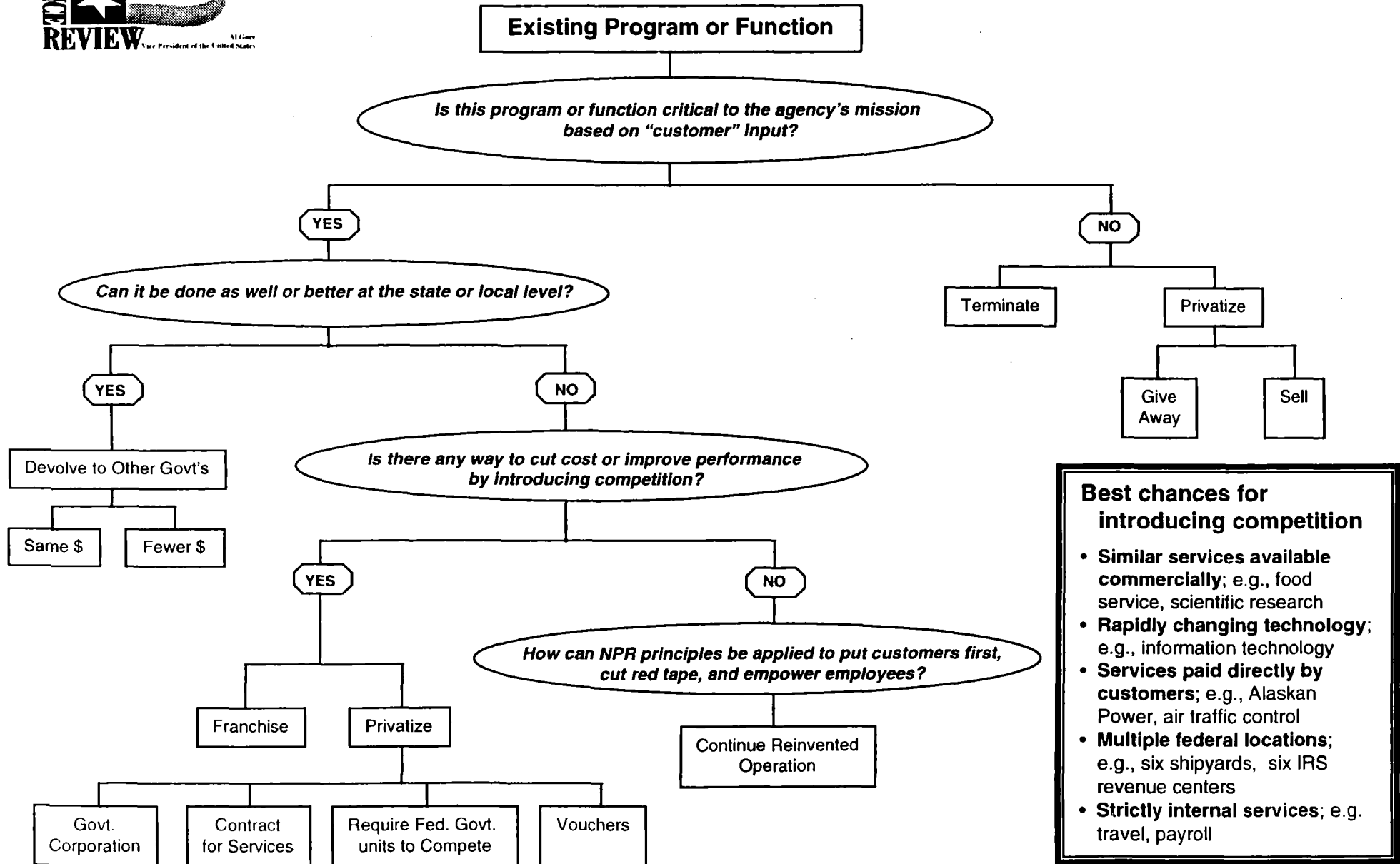
"examine the basic missions of government, looking at every single government program and agency to find and eliminate things that don't need to be done by the federal government [and to] sort out how best to do the things government should continue to do."

The NPR and OMB staffs put together the attached chart to lay out a logical set of steps to go through in analyzing existing government programs or functions. It has helped us to think through the process; we think it would be worth your time to go through its steps mentally as you figure out how to carry out the Vice President's charge.

We hope it helps.

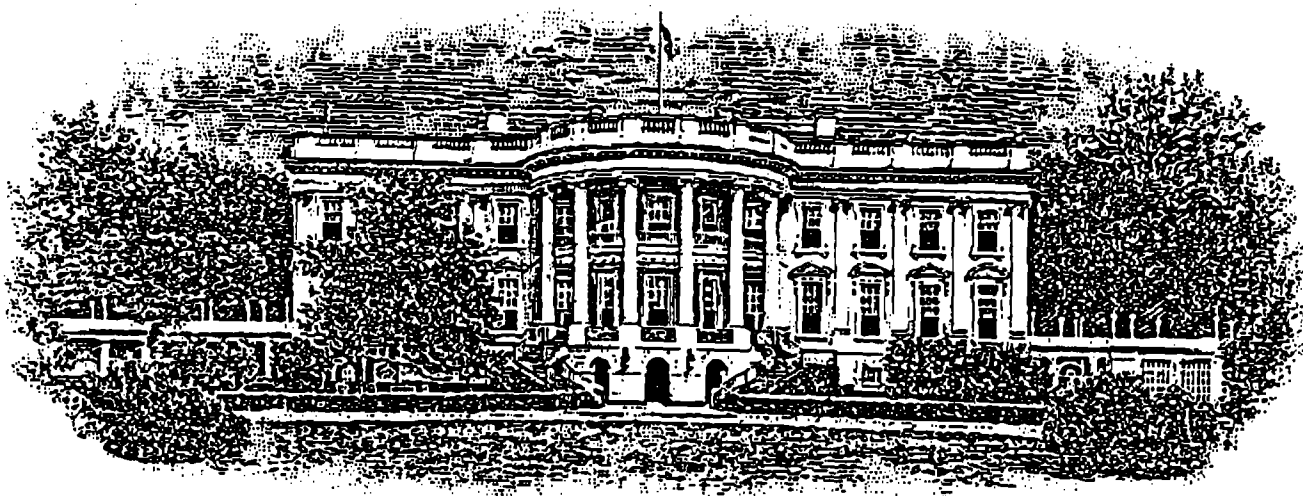
Attachment: Decision Tree Chart

Sample Decision Tree for Analyzing Agency Programs





The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Jennifer Klein / Bill Galster

FAX NUMBER: 6-2878

TELEPHONE NUMBER: _____

FROM: Jeremy Ben-Ami

TELEPHONE NUMBER: 6-5584

PAGES (INCLUDING COVER): 4

COMMENTS: _____

January 24, 1995

MEMORANDUM TO DPC STAFF

From: Jeremy Ben-Ami 
Subject: Assignments to REGO II Teams

Attached please find assignments to the REGO II Teams for the second round of the NPR. As Elaine Kamarck described to us when she spoke at the DPC meeting a couple of weeks ago, these teams will be working parallel to the agency-driven teams. The goal is to set up a healthy tension so that the ideas developed are as bold as possible.

The National Performance Review staff should be in touch shortly to set up initial meetings of the teams. The clusters have been organized to correspond to the OMB PADs. Brian should be involved in all meetings and discussions relating to the three Natural Resources agencies. Mike, Gaynor, and Lynn should coordinate with me on the Human Resources agencies (please invite me to initial meetings). Chris, Jennifer, and Diana should discuss how to coordinate the HHS/health work. Bill will be the lead on the federalism/devolution team, but Paul and Gaynor should work closely together to staff him.

I hope this is clear. Please keep me posted on meetings and progress, and feel free to come to me with questions. We will use one of our staff meetings in February to share thoughts about how the process is going.

cc: Carol Rasco

DPC ASSIGNMENTS TO REGO II TEAMS

IA. Large Agency Team Efforts

National Security and International Affairs

No representation

Natural Resources, Energy, and Science

Cluster Lead: Brian Burke

Agriculture - Brian Burke, Marion Berry

EPA - Brian Burke

Interior - Brian Burke, Mike Schmidt (for BIA)

Human Resources

Cluster Lead: Jeremy Ben-Ami

Education - Gaynor McCown

Labor - Mike Schmidt

Social Security - Lynn Margherio

HHS (non health) - Jeremy Ben-Ami

Health and Personnel

Cluster Lead: Chris Jennings/Jennifer Klein

HHS (Health) - Chris Jennings, Jennifer Klein, Diana Fortuna

VA - Lynn Margherio

General Government

Cluster Lead: Paul Weinstein

Staff on all agencies: Mickey Levitan

IB. Small Agency Team Efforts

Gaynor McCown/Mickey Levitan

II. Federalism and Devolution

Bill Galston, Lead
Paul Weinstein
Gaynor McCown

III. Regulatory Reinvention

Paul Weinstein, Michael Waldman, Leads
Staff already assigned

IV. Implementation of REGO I

No new staff assignments

V. Support: Research and Special Skills Staff

Subsidy Identification: Paul Weinstein
Streamlining: Paul Weinstein
Customer Survey Skills: Paul Weinstein
Privatization: Paul Weinstein, Mickey Levitan
Individual Empowerment: Bruce Reed, Paul Weinstein, Jeremy Ben-Ami

VI. Legislative/Executive Relations

No staff assignments

VII. US Postal Service

Mickey Levitan

**Regulatory Policy Reviews
(As of 1/30/95)**

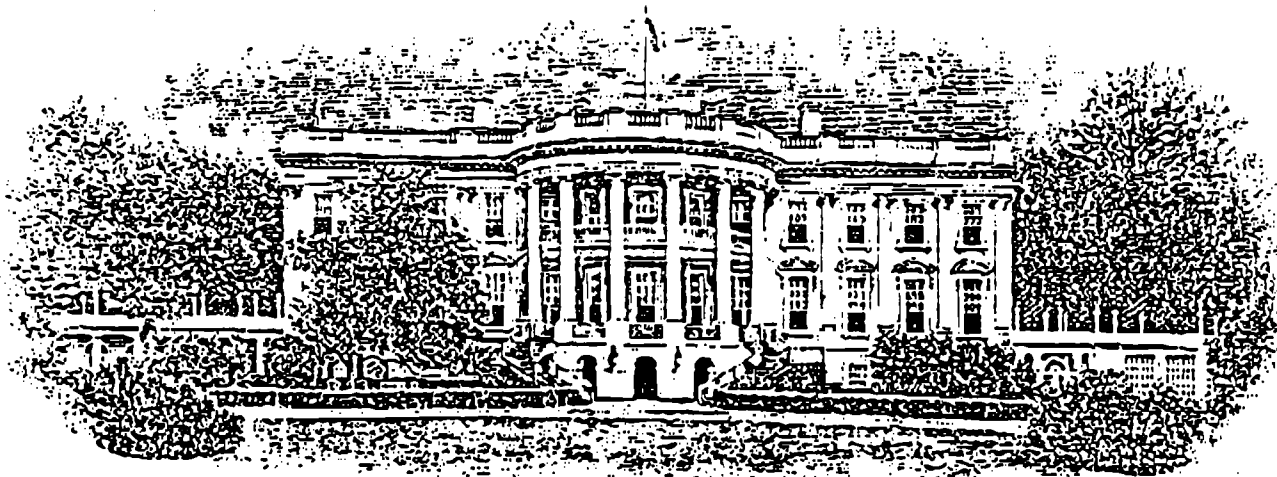
OPTIONAL FORM 99 (7-90)

FAX TRANSMITTA

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Fax changes to Steve Tidrick at 832-0390



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Please distribute to all WW/DPC staffFAX NUMBER: 6-2870TELEPHONE NUMBER: 6-2216FROM: Paul Weinstein (BEAR)

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): 4COMMENTS: _____

NATIONAL PERFORMANCE REVIEW, PHASE II AGENCY PRESENTATIONS

SCHEDULE

as of 02/13/95 (12:30 p.m.)

AGENCY	Agency Package Due to Steering Group Contact	Agency Meeting with Steering Group	Agency-Advisory Group Follow-up Meeting	Agency Revised Package Due	Agency Head Meeting with the VP and OMB Director
NASA DONE	2/08 Wednesday 4:00 pm	2/10 Friday OEOB 248 5:00 - 6:00 pm	2/13 Monday		
No Small Agencies					
INTERIOR Tentative	2/11 2/16 Tuesday 4:00 pm	2/16 Thursday OEOB 248 3:00 - 4:00 pm	2/17 Friday		
14 small agencies	2/13 Monday 4:00 pm	2/16 Thursday OEOB 476 4:00 - 5:00 pm	2/17 Friday		
COMMERCE	2/15 Wednesday 4:00 pm	2/17 Friday OEOB 472 4:00 - 5:00 pm	2/21 Tuesday		
7 small agencies	TP Coordinating Council	2/22 Wednesday OEOB 180 4:00 - 5:00 pm	2/23 Thursday		
DOU	2/21 Tuesday 4:00 pm	2/23 Thursday OEOB 476 4:00 - 5:00 pm			
Selective Service		2/23 Thursday OEOB 248 5:00 - 5:30 pm	2/24 Friday		
VA	2/22 Wednesday 4:00 pm	2/24 Friday OEOB 248 3:00 - 4:00 pm	2/27 Monday		

AGENCY	Agency Package Due to Steering Group Contact	Agency Meeting with Steering Group	Agency-Advisory Group Follow-up Meeting	Agency Revised Package Due	Agency Head Meeting with the VP and OMB Director
Court of Veterans Appeals		2/24 Friday OEOB 248 4:00 - 4:15 pm	2/27 Monday		
SBA Tentative	2/22 - Wednesday 4:00 pm	2/24 Friday OEOB 248 4:30 - 5:30 pm	2/27 Monday		
STATE	2/23 Thursday 4:00 pm	2/27 Monday OEOB 248 3:00 - 4:00 pm	2/28 Tuesday		
12 small agencies		2/27 Monday OEOB 472 4:00 - 5:00 pm	2/28 Tuesday		
EDUCATION	2/24 Friday 4:00 pm	2/28 Tuesday OEOB 248 3:00 - 4:00 pm	3/1 Wednesday		
LABOR Problem	2/24 Friday 4:00 pm	2/28 Tuesday OEOB 472 4:00 - 5:00 pm	3/1 Wednesday		
NSF	2/27 Monday 4:00 pm	3/1 Wednesday OEOB 248 11:00 - 12:00	3/2 Thursday		
HHS Tentative	2/27 Monday 4:00 pm	3/1 Wednesday OEOB 248 1:00 - 2:00 pm	3/2 Thursday		
29 small agencies related to Education 14 small agencies related to Labor 2 small agencies related to NSF		3/2 Thursday OEOB 248 3:00 - 5:00 pm	3/3 Friday		
DOJ	2/28 Tuesday 4:00 pm	3/2 Thursday OEOB 472 5:00 - 6:00 pm	3/3 Friday		

AGENCY	Agency Package Due to Steering Group Contact	Agency Meeting with Steering Group	Agency-Advisory Group Follow-up Meeting	Agency Revised Package Due	Agency Head Meeting with the VP and OMB Director
TREASURY	3/1 Wednesday 4:00 pm	3/3 Friday OEOB 248 3:00 - 4:00 pm	3/6 Monday		
12 small agencies related to Justice 19 small agencies related to Treasury		3/3 Friday OEOB 472 4:00 - 5:00 pm	3/6 Monday		
SSA	3/2 Thursday 4:00 pm	3/6 Monday OEOB 472 3:00 - 4:00 pm	3/7 Tuesday		
FEMA	3/2 Thursday 4:00 pm	3/6 Monday OEOB 248 4:00 - 5:00 pm	3/7 Tuesday		
Postal Service	3/3 Friday 4:00 pm	3/7 Tuesday OEOB 472 3:00 - 4:00 pm	3/8 Wednesday		
Intelligence	3/3 Friday 4:00 pm	3/7 Tuesday OEOB 248 4:00 - 5:00 pm	3/8 Wednesday		
Agriculture Problem	3/6 Monday 4:00 pm	3/8 Wednesday OEOB 180 3:00 - 4:00 pm	3/9 Thursday		
3 small agencies Problem		3/8 Wednesday OEOB 248 4:00 - 5:00 pm	3/9 Thursday		
EPA Tentative	3/7 Tuesday 4:00 pm	3/9 Thursday OEOB 248 1:00 - 2:00	3/10 Thursday		
20 small agencies		3/10 Friday OEOB 248 3:00 - 5:30 pm	3/13 Monday		

THE WHITE HOUSE

WASHINGTON

March 4, 1995

Call Claudia.
How to handle?

MO - 3 PM

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

SUBJECT: Regulatory Reinvention Initiative

Last week, I announced this Administration's plans for further reform of the Federal regulatory system. This is a central part of reinventing our Government. All Americans want the benefits of effective regulation: clean water, safe workplaces, wholesome food, sound financial institutions. But, too often the rules are drafted with such detailed lists of dos and don'ts that the objectives they seek to achieve are undermined. Clear goals and cooperation would work better. Too often, businesses, especially small ones, face a profusion of overlapping and sometimes conflicting rules.

We have already made real progress in reforming regulation. This memorandum will build on the regulatory philosophy set forth in Executive Order No. 12866 of September 30, 1993, "Regulatory Planning and Review," which is premised on the recognition of the legitimate role of government to govern, but to do so in a focused, tailored, and sensible way.

In the year and a half since that order was signed, we have opened the rulemaking process to the public, we have increased cooperation and coordination among the Federal agencies, and we have seen good processes produce good decisions.

However, not all agencies have taken the steps necessary to implement regulatory reform. To reaffirm and implement the principles of Executive Order No. 12866, regulatory reform must be a top priority.

Accordingly, I direct you to focus on the following four steps, which are an integral part of our ongoing Regulatory Reform Initiative.

FIRST: CUT OBSOLETE REGULATIONS

I direct you to conduct a page-by-page review of all of your agency regulations now in force and eliminate or revise those that are outdated or otherwise in need of reform. Your review should include careful consideration of at least the following issues:

- o Is this regulation obsolete?
- o Could its intended goal be achieved in more efficient, less intrusive ways?
- o Are there better private sector alternatives, such as market mechanisms, that can better achieve the public good envisioned by the regulation?
- o Could private business, setting its own standards and being subject to public accountability, do the job as well?
- o Could the States or local governments do the job, making Federal regulation unnecessary?

This review should build on the work already being done by your agencies under section 5 of Executive Order No. 12866.

Your regulatory review task force should be headed by one of your appointees who should be given your full support and should, to the extent practicable, be freed of other duties.

I further direct you to deliver to me by June 1 a list of regulations that you plan to eliminate or modify with a copy of the report sent to Sally Katzen, Administrator of the Office of Information and Regulatory Affairs (OIRA). The list should distinguish between the regulations that can be modified or eliminated administratively and those that require legislative authority for modification or elimination.

SECOND: REWARD RESULTS, NOT RED TAPE

I direct you to change the way you measure the performance of both your agency and your frontline regulators so as to focus on results, not process and punishment. For example, Occupational Safety and Health Administration (OSHA) inspectors should not be evaluated by the number of citations they write, nor should officials of the Consumer Product Safety Commission be judged by the number of boxes of consumer goods that are detained in shipment. This change in measurement should involve a two-step process.

First, you should identify appropriate performance measures and prepare a draft in clear, understandable terms, of the results you are seeking to achieve through your regulatory program. The draft should be circulated to frontline regulators for review and comment. This is the same work needed to meet the requirements of the Government Performance and Results Act of 1993.

Second, you should evaluate and reward employees based on the realization of those measures/goals.

By no later than June 1, I direct you to (a) eliminate all internal personnel performance measures based on process (number of visits made, etc.) and punishment (number of violations found, amount of fines levied, etc.), and (b) provide to the National Performance Review (NPR) staff a catalogue of the changes that you are making in existing internal performance evaluations to reward employees. You should also provide material describing shifts in resource allocation from enforcement to compliance.

THIRD: GET OUT OF WASHINGTON AND CREATE GRASSROOTS PARTNERSHIPS

I direct you to promptly convene groups consisting of frontline regulators and the people affected by their regulations. These conversations should take place around the country -- at our cleanup sites, our factories, our ports.

I further direct you to submit a schedule of your planned meetings to the NPR staff by March 30 and work with NPR in following through on those meetings.

FOURTH: NEGOTIATE, DON'T DICTATE

It is time to move from a process where lawyers and bureaucrats write volumes of regulations to one where people work in partnership to issue sensible regulations that impose the least burden without sacrificing rational and necessary protections. In September 1993, I asked each of you to identify at least one rule that could be conducted through negotiated rulemaking (or to explain why such could not be done) in order to promote consensual rulemaking as opposed to the more traditional rulemaking that has dominated the regulatory arena.

I now direct you to expand substantially your efforts to promote consensual rulemaking. To this end, you should submit to OIRA, no later than March 30, a list of upcoming rulemakings that can be converted into negotiated rulemakings. I have directed Sally Katzen to review your lists with a view toward making clear to the regulated community that we want to work together productively on even the most difficult subjects.

To facilitate our ability to learn from those affected by regulation, I will amend Executive Order No. 12838 (which requires agencies to reduce the number of advisory committees that they use and to limit the future use of such committees) to allow for advisory committees established for negotiated rulemakings.

I also intend to take additional steps to increase our ability to learn from those affected by regulation. While many laws and rules that limit the ability of regulators to talk with those being regulated were imposed to curb abuse, they now often serve as a barrier to meaningful communication between the regulators and the regulated. To address this problem, and to promote consensus building and a less adversarial environment, I direct you to review all of your administrative *ex parte* rules and eliminate any that restrict communication prior to the publication of a proposed rule -- other than rules requiring the simple disclosure of the time, place, purpose, and participants of meetings (as in Executive Order No. 12866). We will also begin drafting legislation that will carve out exemptions to the Federal Advisory Committee Act to promote a better understanding of the issues, such as exemptions for meetings with State/local/tribal governments and with scientific or technical advisors.

I also ask you to think about other ways to promote better communication, consensus building, and a less adversarial environment. Please send your ideas to the Office of the Vice President.

As I said on Tuesday, February 21, 1995, you are to make regulatory reform a top priority. Good government demands it and your full cooperation is crucial.

William J. Clinton