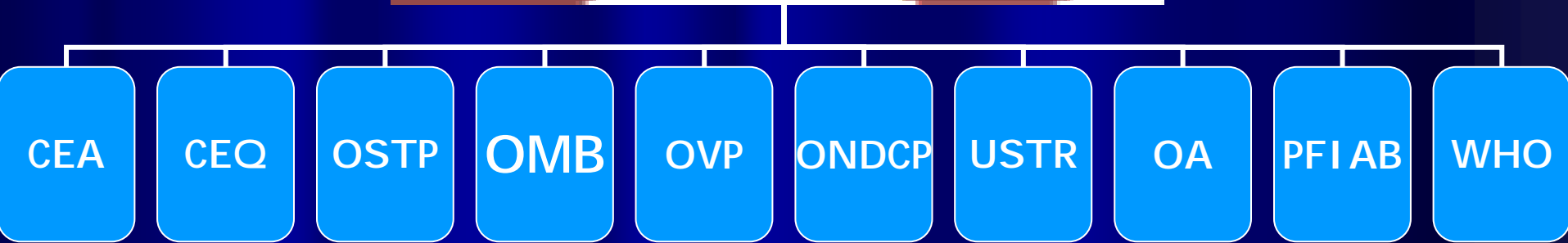# Science and Regulatory Policy at OMB
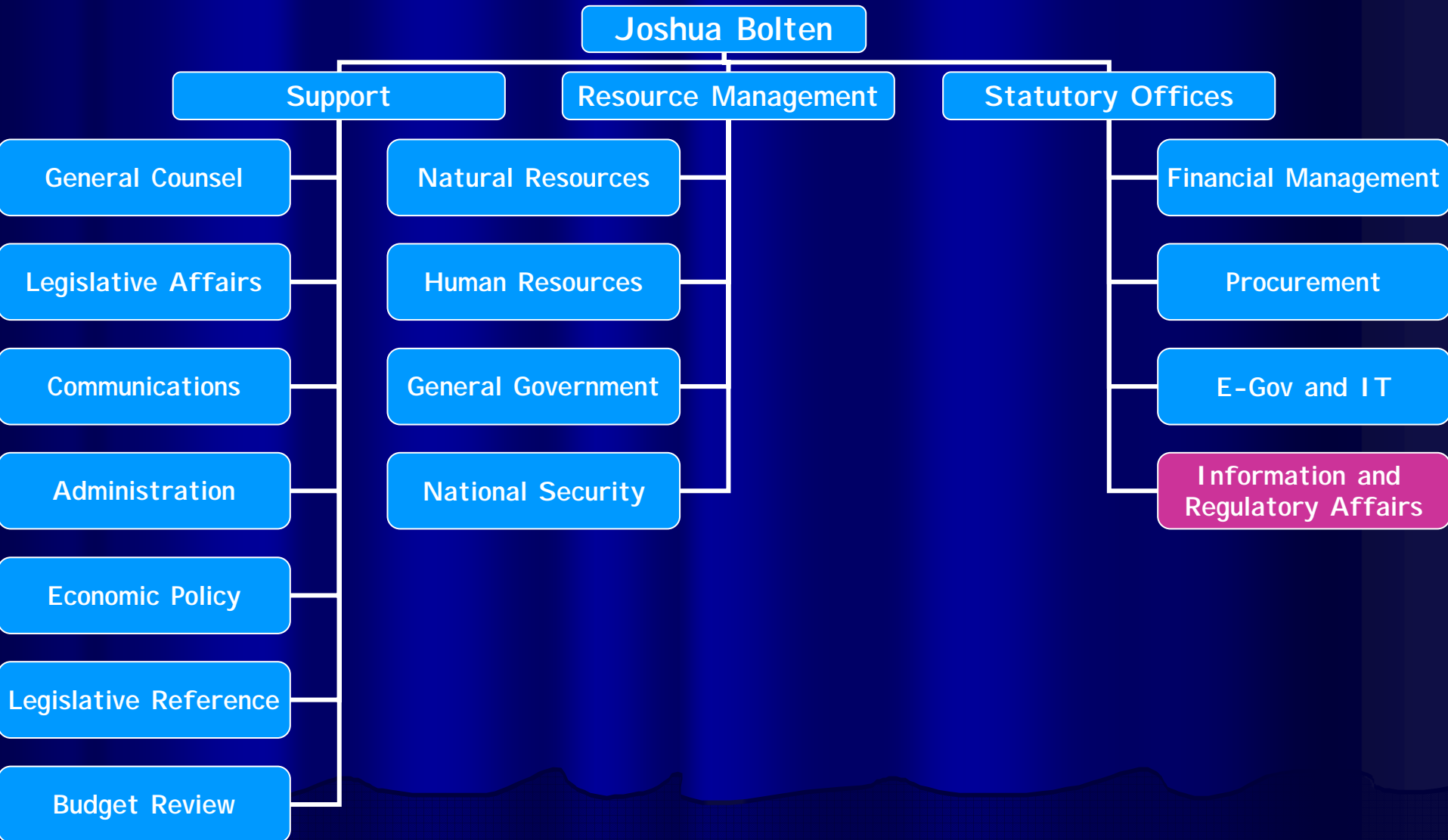
John D. Graham, PhD

Administrator

Office of Information and Regulatory Affairs

Office of Management and Budget

Executive Office of the President

The Executive Office of the President (EOP)

| CEA | CEQ | OSTP | OMB | OVP | ONDCP | USTR | OA | PFIAB | WHO |

Office of Management and Budget (OMB)

Joshua Bolten

- **Support**
- **Resource Management**
- **Statutory Offices**

Support	Resource Management	Statutory Offices
General Counsel	Natural Resources	Financial Management
Legislative Affairs	Human Resources	Procurement
Communications	General Government	E-Gov and IT
Administration	National Security	Information and Regulatory Affairs
Economic Policy		
Legislative Reference		
Budget Review		

Office of Information and Regulatory Affairs (OIRA)

John D. Graham
Administrator

Branch Chief
Info Policy and
IT

Branch Chief
Statistical &
Science Policy

Branch Chief
Natural Resources,
Energy & Ag

Branch Chief
Health Transportation
& General Govt

Desk
Officers

Statistical
Consultants

Scientific
Consultants

Desk
Officers

Economic
Consultants

Desk
Officers

Economic
Consultants

OIRA History

- President Carter and "Paperwork Reduction"

- President Reagan and "Regulatory Relief"

- President Clinton Reaffirms OIRA's Role with Executive Order 12866 (EO 12866)

How Regulation Has Changed 1980-2005

- Decline of economic regulation

- Rise of science-based regulation

- Majority of rules address public health, safety, environment, and homeland security (FDA, CMS, OSHA, EPA, NHTSA, DHS)

New Expertise at OIRA

- Toxicology
- Epidemiology
- Risk Modeling
- Engineering
- Environmental Science
- Public Health

Paperwork Reduction Act

- **Purpose:** To improve the quality and practical utility of information required by the Federal Government, and to reduce the paperwork burden on the public.

    - Agencies submit "information collection" requests
    - OMB has approval authority over agency requests
    - OMB reviews about 2,000 collection requests per year

Paperwork Reduction Act

- The OIRA role is to ensure that the information collected is:
  - Least Burdensome
  - Not Duplicative
  - Has Practical Utility

- 60 day public notice in the Federal Register is required before OMB begins review. After receipt, OMB has 60 days for review.

Regulatory Planning and Review

- Agencies submit "significant" regulatory actions to OIRA for up-to-90 day review.

- OIRA examines benefit-cost analysis and considers views of all federal agencies.

- OIRA "clears" or "returns" rules for further deliberation; negotiations are common.

- OIRA reviews about 500 rules per year.

What we look for during review...

- Were regulatory alternatives considered?
- Was the rule based on best available, peer-reviewed science?
- Were benefits and costs identified, quantified and weighed?
- Were qualitative, ethical, and legal factors considered?

Transparency of OIRA's Process

- OMB's public website each day shows which rules are under formal review at OMB and which have been cleared.

- OMB's website notes which outside groups have recently lobbied OIRA: providing their names, organizations, date of the meeting, and the rule under discussion.

- All written information given to OMB while a rule is under review is sent to the agency, placed in our public docket and posted on our website.

- Return letters sent to the agencies outlining our concerns with rules we send back are posted on our website.

Information Quality Law (2000)

- Directed OMB to issue government-wide guidelines to Federal agencies for ensuring and maximizing the:
  - **Quality**
  - **Objectivity**
  - **Utility** and
  - **Integrity** of information disseminated by Federal agencies.

Information Quality Guidelines

- Agencies must meet basic information quality standards.

- The more important the information, the higher the quality standards should be.

Information Quality Guidelines

- The Guidelines recognize that high quality comes at a cost and agencies should weigh the costs and benefits of higher information quality.

- Influential Information:
  - **Influential** means that the agency can reasonably determine that dissemination of the information **will have or does have a clear and substantial impact on important public policies or important private sector decisions.**

- Influential information, as defined by agencies, needs to meet additional quality standards including reproducibility.

IQ Status

- Agency Guidelines became effective Oct 2002.

- Approximately 35 substantial requests for correction were submitted to the agencies in FY03.

- Multiple agencies affected: USDA, Commerce, HHS, Education, Interior, Transportation, and EPA.

- Requests for correction have come from private citizens, corporations, trade associations, NGO's, and even other government agencies.

Examples of IQ Correction Requests

- Examples of some IQ correction requests where scientific input helped with review:
  - Atlantic Salmon
  - Anthraquinone
  - Fluoridation
  - Fluoroquinolines
  - Nickel
  - Barium
  - Perchlorate
  - Atrazine

Information Quality Bulletin for Peer Review

- The goal of the bulletin is to enhance the quality and credibility of the government's scientific information
  - Bulletin establishes minimum standards for when peer review is required
  - Describes the types of peer review that should be considered by agencies
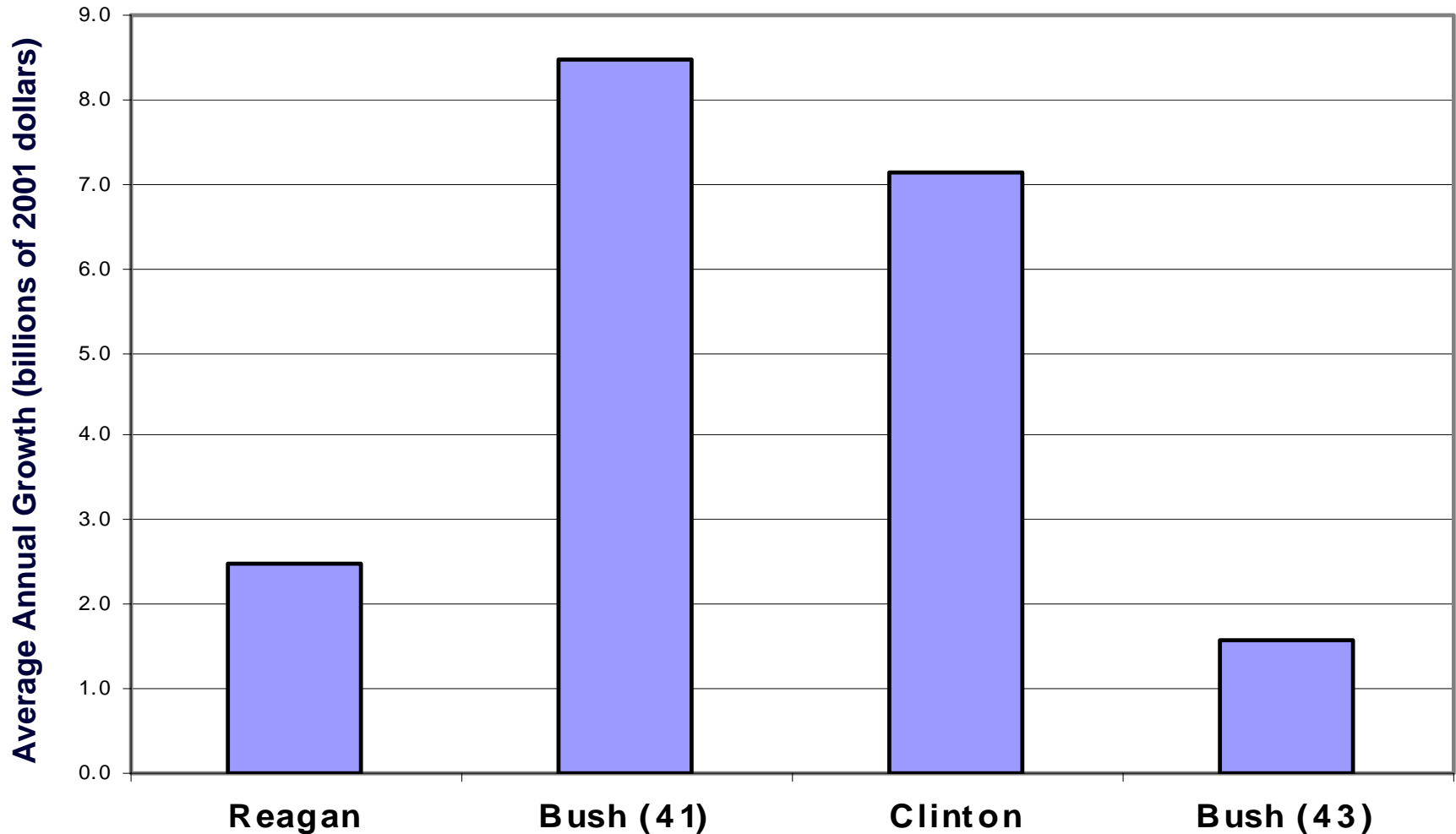 - Establishes a transparent process for disclosure of agency peer review planning

Process for Developing the Peer Review Bulletin

- OMB published a final bulletin for peer review on December 16, 2005
  - First proposed September 2003
    - 187 public comments
    - Workshop at the National Academy of Sciences
  - Revised April 2004
    - 57 public comments

Final Peer Review Bulletin

- Provides discretion to the federal agencies in determining what type of peer review mechanism is appropriate for specific information products.

- Provides exemptions for time-sensitive medical, public health and safety information.

- Defines a more transparent process for public participation in peer review planning.

- Requires the most rigorous form of peer review for highly influential scientific assessments.

Average Annual Cost Growth of Major Federal Regulations by Administration

Examples of Good Regulations

- Trans-Fat Food Labeling (FDA)

- Side Impact Airbags (NHTSA)

- Off-Road Diesel (EPA)

- Fuel Economy of SUV's (NHTSA)

General Resources

- **www.omb.gov**

- Executive Order 12866 – Regulatory Planning and Review 58 Fed. Reg. 51735 (October 4, 1993).

- Economic Analysis of Federal Regulations Under Executive Order 12866 ("Best Practices Guidance"), January 11, 1996. http://www.whitehouse.gov/omb/inforeg/riaguide.html

- Regulations under review listed at: http://www.whitehouse.gov/library/omb/OMBREGSP.html

- ICRs under review listed at: http://www.whitehouse.gov/library/omb/OMBPPWKP.html

- http://www.whitehouse.gov/omb/inforeg/