

US Experience with Regulatory Impact Analysis

John F. Morrall III, Ph.D.

Pretoria

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John F. Morrall III, Ph.D.

Worked for six Presidents of the United States in the Executive Office of the President on RIA s.

Began working at Office of Management and Budget (OMB) as an economist in 1981 when the Office of Information and Regulatory Affairs (OIRA) was established in OMB.

1989-2008: Acting Deputy Administrator and Branch Chief for OIRA. The Deputy Administrator is the highest career job in OIRA.

Responsible for reviewing the regulations and regulatory impact analyses issued by the Departments and agencies of the Federal government under E. O. 12866.

Before becoming Acting Deputy Administrator in June 2006, Branch Chief for Health, Transportation and General Government.

Lead author for OMB's annual *Report to Congress on the Costs and Benefits of Federal Regulations*.

Advised APEC, OECD, EU, Sigma, and dozens of governments on the US regulatory oversight system.

U.S. Approach to Regulatory Policy

□ Centralized Management and Leadership

- Emphasizes the importance of and adherence to regulatory principles and procedures.

□ Transparency and Accountability

- Addresses concerns about undue influence and allows all interested parties to be heard.

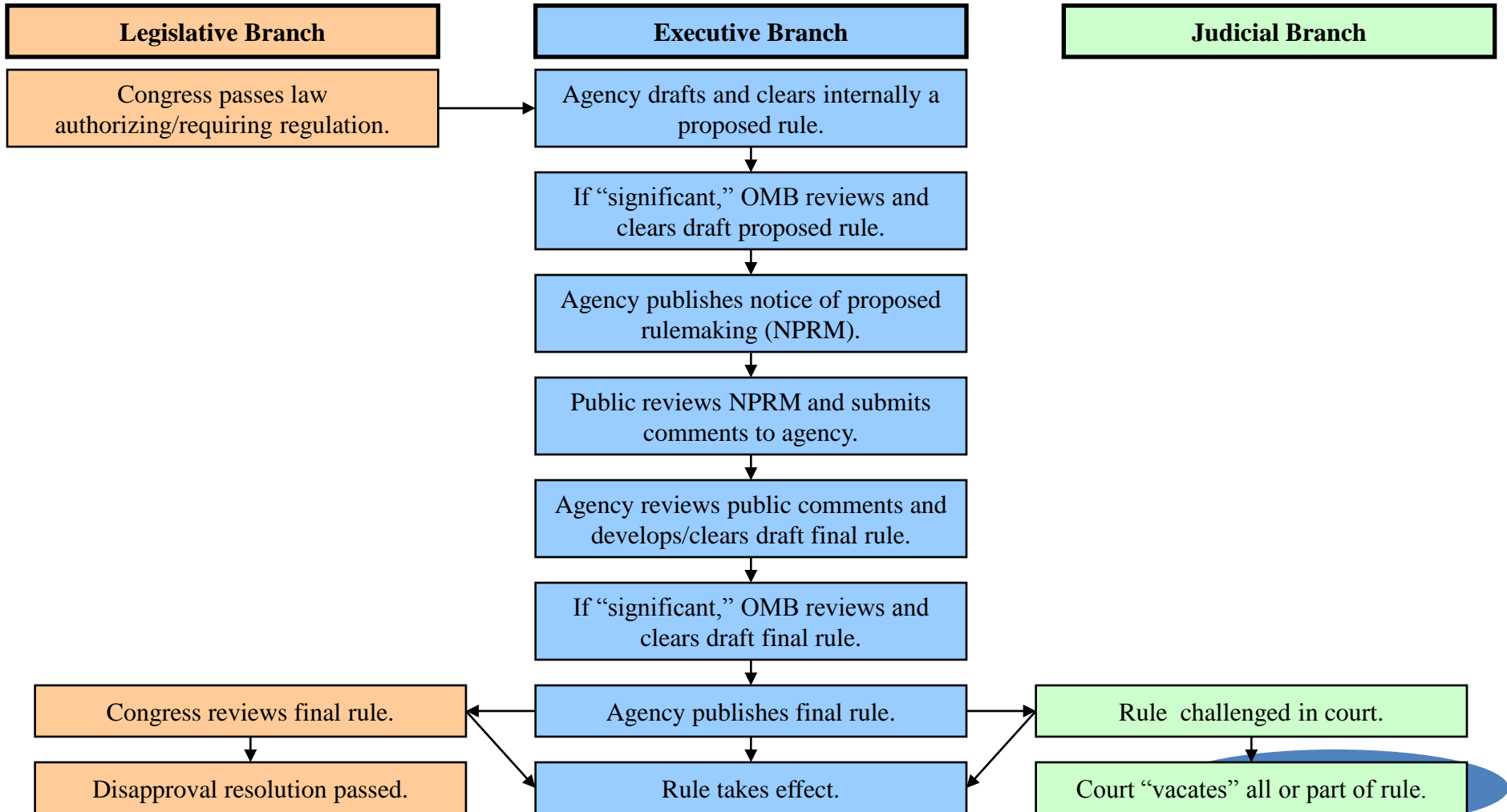
□ Regulatory Impact Analysis

- Contributes to more informed policy decisions and promotes efficiency.

□ “Smarter Regulation”

- Adopt good rules; modify and rescind existing rules to improve cost effectiveness.

Federal Rulemaking Process



Office of Management and Budget



- ❑ Assists the President in the development and implementation of budget, program, management, and regulatory polices.
 - ❑ Develops the President's annual budget submission to Congress.
 - ❑ Assists the President in managing the Executive Branch, developing the Administration's position on legislation before Congress and executing the law.
 - ❑ Provides high quality regulatory analysis.
- ❑ **History**
 - ❑ 1921: Bureau of the Budget (BoB) established within the Treasury Department.
 - ❑ 1939: BoB moved from Treasury to the Executive Office of the President.
 - ❑ 1970: BoB reorganized into the Office of Management and Budget.
 - ❑ 1980: Office of Information and Regulatory Affairs (OIRA) established within OMB by Paperwork Reduction Act.

Centralized Management and Leadership

□ Presidential Oversight of Government Regulatory Policy

- President Ford: Required, for the first time, regulatory impact analysis (RIA) requirement for major regulations (over \$100 million in impact).
- President Carter: Established the Regulatory Analysis Review Group.
- President Reagan: Solidified regulatory oversight authority within the White House, issuing Executive Order 11291, which required OMB review and approval of rules.
- President George H.W. Bush: Continued the Reagan Executive Order.
- President Clinton: Issued Executive Order 12866, which focused OMB oversight on “significant” rules and increased the disclosure of contacts with outside parties.
- President George W. Bush: Maintained the Clinton Executive Order that requires the agencies to do RIAs and send significant regulations to OMB for review. Added “prompt” letters.
- President Obama: Continued EO 12866 and reaffirmed centralized review but asked for recommendations to improve the EO.

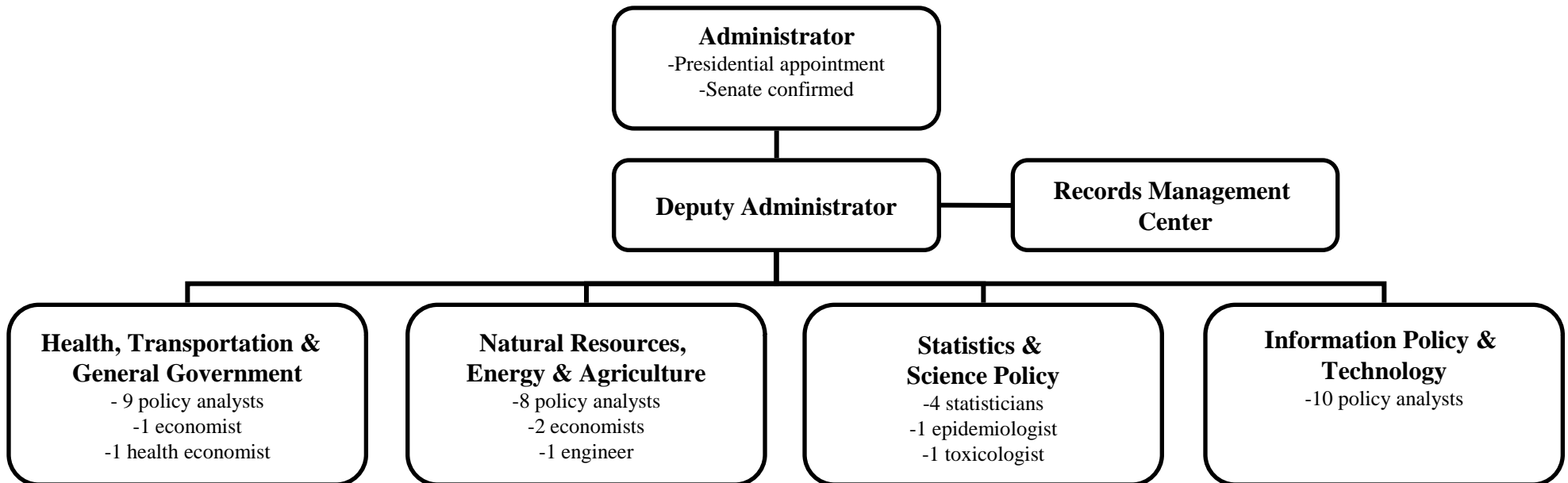
Centralized Management and Leadership

❑ Role of the Office of Information and Regulatory Affairs

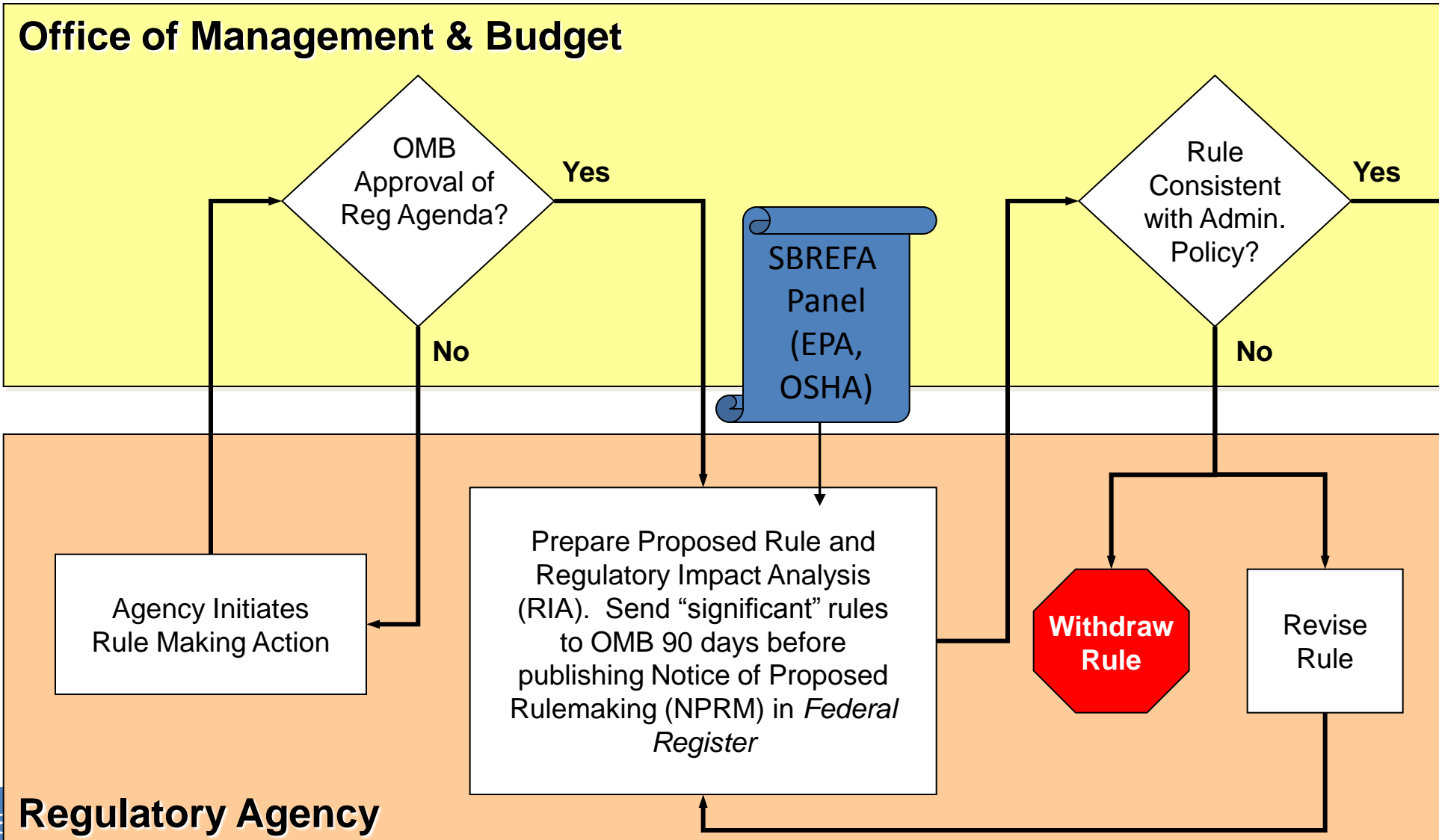
- ❑ OIRA was established by the Paperwork Reduction Act of 1980, partially in response to the explosion in regulation that occurred in the 1970s and earlier in the U.S.
- ❑ As part of the Office of Management and Budget, OIRA is a central body that has special standing with the agencies.
- ❑ OIRA manages and coordinates Federal rulemaking, and oversees Federal information management, statistical policy, and information technology policy.
- ❑ Administrator is a PAS (Presidentially appointed Senate confirmed). In press often called the “Regulatory Czar”
- ❑ OIRA often called in the press “obscure but powerful”

Centralized Management and Leadership

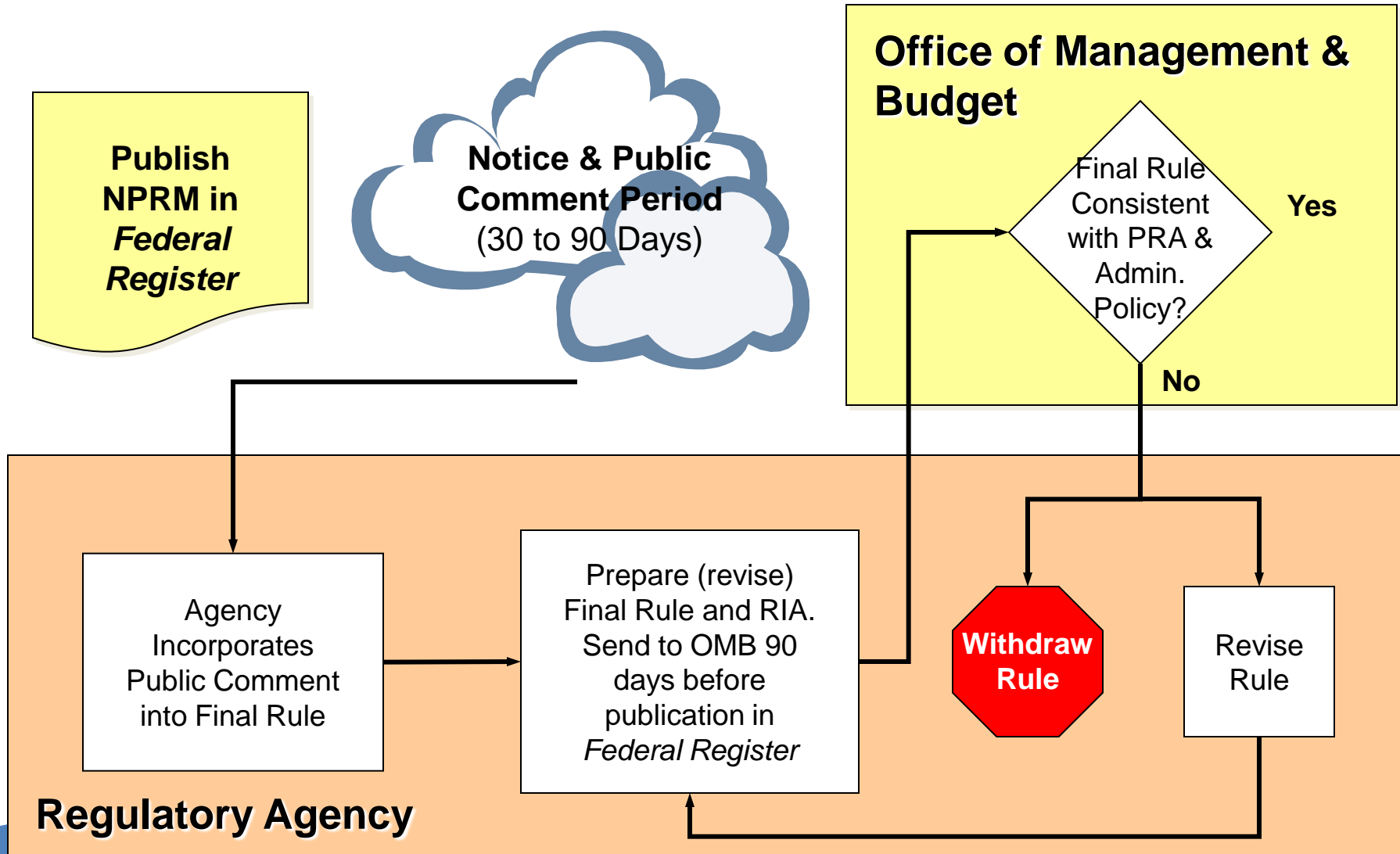
Office of Information and Regulatory Affairs



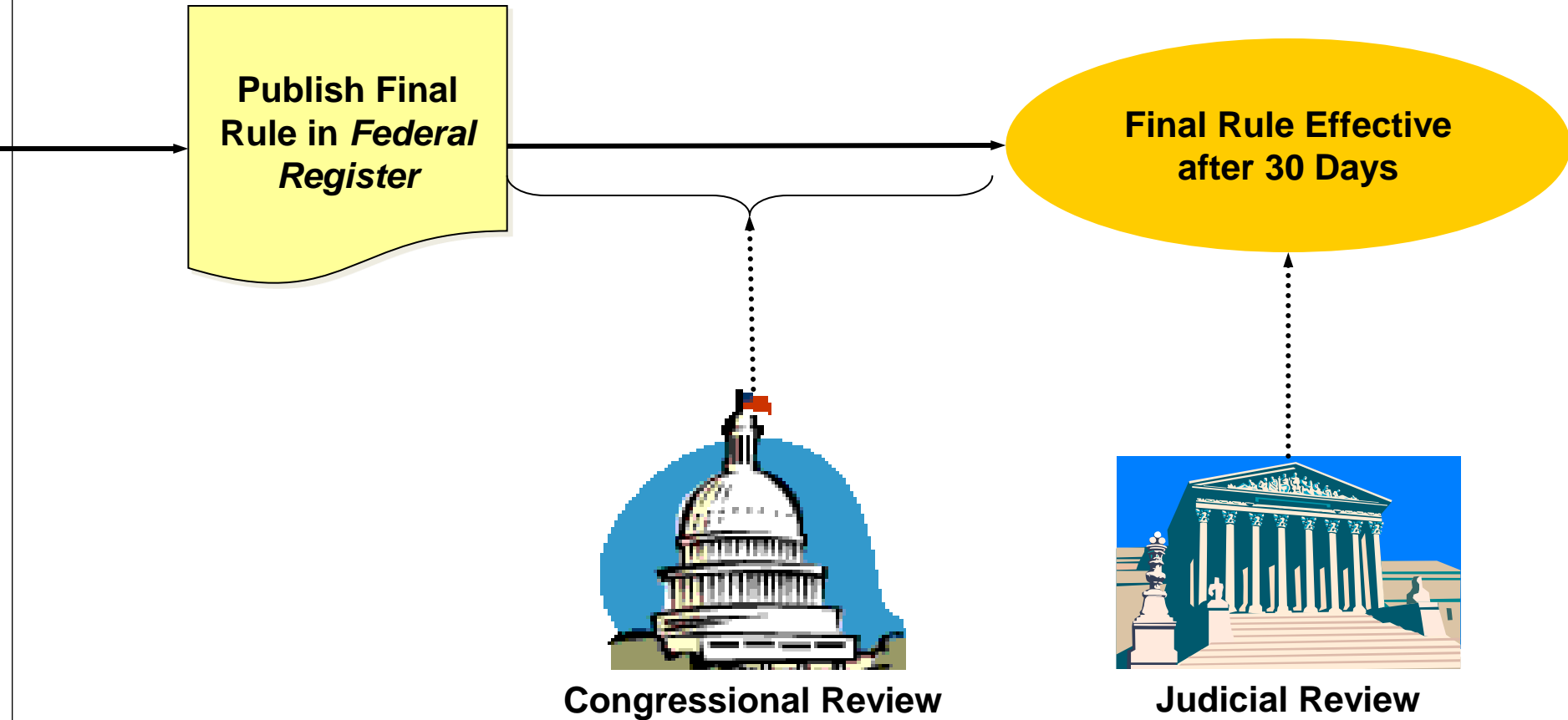
Birth of a Regulation, Initiation Phase



Notice, Comment, & Finalization



Publication & Possible Review



Centralized Management and Leadership

- ❑ Presidential Executive Order 12866 (September 30, 1993)
 - ❑ Executive Order 12866 on Regulatory Planning and Review governs OMB's oversight of agency rulemaking, requiring OMB review of "significant" agency regulatory actions.
 - ❑ Agencies submit draft significant regulations (both proposed and final) to OIRA for an up-to-90-day review before publishing them in the *Federal Register*.
 - ❑ OIRA reviews 500-700 regulations per year—those determined to be significant—out of about 2,200 that are issued.
 - ❑ About 70-100 of the regulations reviewed are "economically significant" (over \$100 million per year in economic effects). These require a Regulatory Impact Analysis (RIA).
 - ❑ During its review, OMB examines the RIA and the regulation and makes suggestions to improve both the RIA and the rule's cost-effectiveness and to make sure that it comports with the underlying statute, the Executive Order's principles and the President's priorities.
 - ❑ If the agency refuses to make changes or needs more time to make the changes, OMB can return the rule to the agency for reconsideration.
 - ❑ All done **"To the extent permitted by law"**

Regulatory Transparency and Accountability

□ Administrative Procedure Act of 1946

- The Act requires that agencies go through a notice and comment process open to all members of the affected public, both U.S. and foreign.
- Before agencies can issue a final regulation, they must respond to the public comments, make sure that the final regulation is a logical out-growth of the proposal and the public record, and is not arbitrary or capricious.
- The public record is used by the courts in settling any challenge to the regulations brought by the affected public.

Regulatory Transparency and Accountability

❑ Disclosure of Information Under Executive Order 12866

- ❑ The public can consult OMB's website and learn each day which rules are under formal review at OMB and which have been cleared.
http://www.whitehouse.gov/omb/inforeg_regmatters/
- ❑ OMB's website notes which outside groups have recently lobbied OIRA on rules under review.
- ❑ All written information given to OMB while a rule is under review is sent to the agency, placed in OIRA's public docket reading room, and posted on its website.
- ❑ Return letters sent to the agencies outlining concerns with are posted on website. Prompt letters are also posted.
- ❑ All agency rulemakings and public comments can be found at [Regulations.gov](http://www.Regulations.gov)

Regulatory Transparency and Accountability

❑ Each Branch of Government has a Role

- ❑ Agencies demonstrate to OMB, acting as an advisor to the President, that their regulatory analysis is of high quality and supports a finding that the regulation is likely to maximize net benefits and is in compliance with the law.
- ❑ After OMB concludes its review of a regulation and it is published in the *Federal Register*, Congress reviews it under the Congressional Review Act.
- ❑ After a rule goes into effect, affected parties can bring suit against the agency issuing the rule to have the courts reverse or mandate it back to the agency because the agency violated the APA's process requirements, the statute that authorized the rule, or the U.S. Constitution.
- ❑ The Regulatory Right-to-Know Act requires OMB to issue a report to Congress each year estimating the costs and benefits of regulations in the aggregate, by agency and agency program, and by regulation.

Regulatory Impact Analysis

- ❑ Required of Departments and Agencies for regulations with impact of over \$100 million issued by Executive Branch agencies (independent agencies and Congress not covered)

- ❑ Basic Goals
 - ❑ Maximize net benefits to society—or at least ensure that benefits justify costs.
 - ❑ Promote economic efficiency by regulating where markets fail, and when regulating, by using cost-effective and market-based approaches.
 - ❑ Increase the transparency of the regulatory system.
 - ❑ Use in Executive, Judicial, and Congressional decisions
 - ❑ Use in retrospective evaluations

Regulatory Impact Analysis

□ Elements of a Regulatory Impact Analysis (scorecard)

Statement of need for the proposed rule that identifies the nature and significance of the problem (e.g., correction of the market failure , removing distributional unfairness, or promoting privacy or personal freedom).

- Examination of alternative approaches to addressing the problem.
- Analysis of the costs and benefits of each alternative.
- Analysis of the costs and benefits of proposed action.
- Discounting by 3% and 7%.
- Cost-effectiveness analysis (CEA) if health, safety, or environmental regulation.
- Formal uncertainty analysis for over \$1 billion costs (Monte Carlo analysis)
- Distributional effects (who gains who loses) estimated by income, geography, age, etc.

Regulatory Impact Analysis

- ❑ OMB Circular A-4: Guidelines for the Development of Regulatory Analysis
 - ❑ Issued September 2003 after Notice and Comment, peer review, and agency comments
 - ❑ Undated versions issued in 1987, 1996, and 2000.
 - ❑ Emphasizes careful consideration of qualitative and intangible values.
- ❑ Expanding OIRA's Staff
 - ❑ Traditionally, OIRA's professional staff consisted mostly of economists, public policy analysts, and lawyers.
 - ❑ OIRA hired PhDs with expertise in risk assessment -- epidemiology, toxicology, public health.

Regulatory Impact Analysis

- Quality Control
 - Review, revise, and/or return
 - Interagency review
 - Public comment period
 - Judicial review
- Scorecard
 - Eight elements tracked internally for staff bonuses
 - May publish scorecard for rating agencies

Regulatory Impact Analysis

- Types of RIAs
 - Competition Analysis for “economic” regulation
 - Transfer analysis for fiscal and distributional impacts using “administrative” regulations with primary impact on the budget
 - Benefit-Cost Analysis and/or Cost-Effectiveness Analysis for “social” regulation
 - Regulatory Flexibility Analysis for regulations with significant impact on small and medium size businesses
- Depth of Analysis proportionate to potential impact
 - < \$100 million, >\$100 million, and >\$1 billion

RIA in Action: the Case of Trans Fat(1)

- Regulation issued 2003 required firms to label separately trans fat content of foods in nutrition facts panel
- A 1999 Clinton proposal to add trans fat to sat fat content had stalled at the Food and Drug Administration
- First OIRA “prompt letter” September 2001 based on BCA analysis in 1999 PRIA and new risk assessment evidence that trans fat intake caused Chronic Heart Disease (CHD)
- Using CEA: I had published several cost per statistical life saved (CSLS) “league” tables and found trans fat labeling to be a very cost-effective potential regulatory action

RIA in Action: the Case of Trans Fat

(2)

- Of 76 final rules issued, 32 above \$7m per CSLS and 27 above \$21m per CSLS. Trans fat less than \$10k
- \$7 million based on willingness-to-pay (WTP) and \$21 million based on Health-Health Analysis fatal cutoff estimate
- RIA for the new improved 2003 rule.
 - Based on consumer surveys trans fat was about 2.5% of energy intake with 2.0% being added by food processors
 - Reformulation of margarine and consumer avoidance estimated very conservatively to reduce intake by 0.04% (1/50th of total)

RIA in Action: the Case of Trans Fat

(3)

- After doing risk-risk analysis due to substitution of other fats the net reduction in CHD is from .05% to .1% using risk estimates for CHD from various fats
- Given 1.1 million heart attacks per year in the US (40% fatal), labeling reduces from 200 fatal and 400 nonfatal heart attacks per year to 480 fatal and 720 nonfatal depending on the mechanism assumed (LDL or both LDL and HDL).
- Cost analysis based on the number of labels needing change (300,000), products needing testing (60,000) and costs of voluntary reformulation (45 products)
 - One time costs of \$140m to \$250m

RIA in Action: the case of Trans Fat(4)

Benefits

- \$230 million to \$2,839 million per year
- Reasons for range:
 - Discount rate of 3% and 7%
 - Life years gained and QALYs
 - WTP and Medical costs
 - Two risk reduction methods
- Shows Cost-effectiveness of **Nudge**

Costs

- \$9 million to \$26 million per year
- Weaknesses
 - Distribution analysis (affect on poverty) not done
 - Alternatives not estimated

Recent Developments with RIA

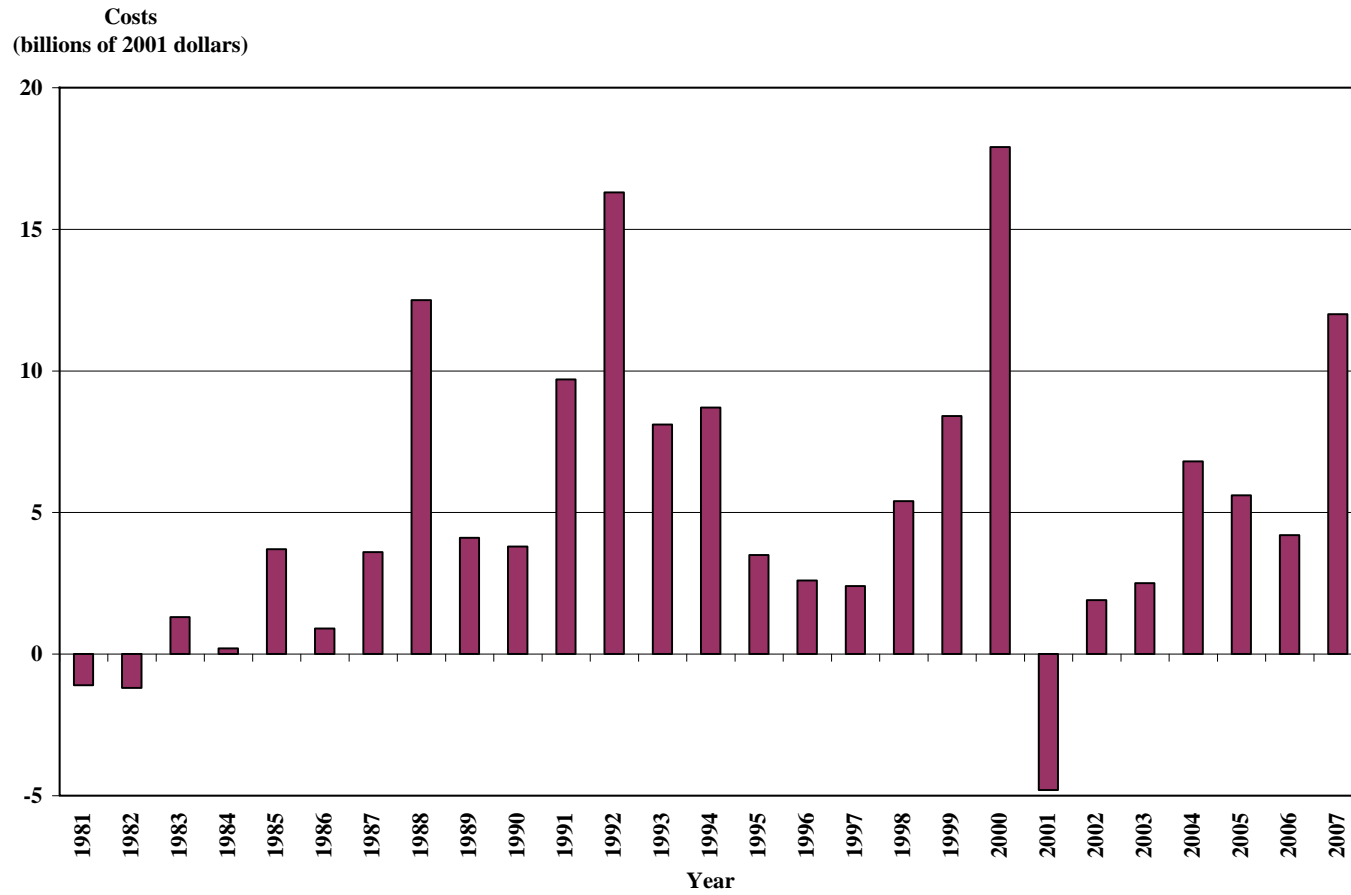
- ❑ President Bush Amended EO 12866, Regulatory Planning and Review, on January 18th 2007 with EO 13422
 - ❑ Required agencies to inform OMB of significant guidance documents.
 - ❑ Required agency Regulatory Policy Officers (RPOs) be Presidential Appointees.
 - ❑ Required a RPO to authorize commencement of a rulemaking.
 - ❑ Required identification of market failure

- ❑ President Obama revoked EO 13422 on January 30, 2009.
 - ❑ Put Vice President back in charge (WH Chief of Staff during Bush)
 - ❑ Also asked for suggestions to improve regulatory review and RIAs.
 - ❑ Nominated Cass Sunstein, Professor of Law at Harvard Law School.

Recent Developments with RIA

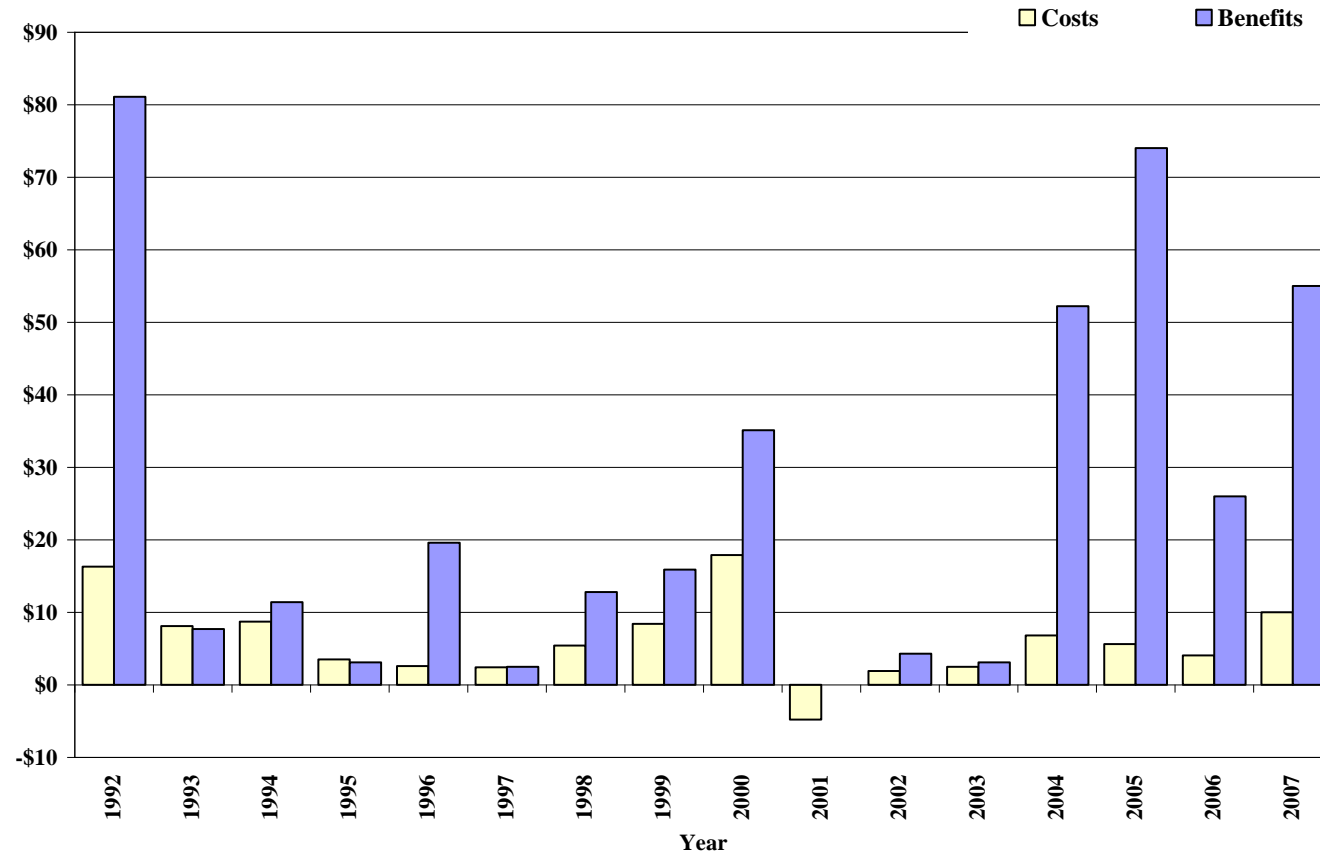
- President Obama asked for suggestions on:
 1. Relationship between OIRA and the agencies
 2. Disclosure and Transparency
 3. Public –participation
 4. Role of cost-benefit analysis
 5. Role of distributional concerns, fairness, and concerns for future generations
 6. Ways to reduce undue delay
 7. Role of behavioral science
 8. Identifying best tools
- Got 168 comments from public and agencies

Costs of Regulations Based on RIAs



Improving Regulatory Quality : Costs and Benefits of Major Rules (1992-2007)

Costs and Benefits
billions of 2001 dollars



Regulatory Quality Leads to Strong Macro Performance

- ❑ Was the original justification for the US regulatory reform program during the stagflation days of the mid 1970s and has been a Presidential priority since then.
- ❑ Since the mid 1980s, US economic performance (per capita growth, inflation, and employment) has been one of the best in the industrialized world, contrary to the per capita income convergence theory.
- ❑ Studies by the World Bank (*Doing Business* series), the OECD, Heritage Foundation, and the Fraser Institute consistently find positive impacts to improvement in regulatory quality. Countries with flexible and efficient regulatory systems coupled with strong property rights have the best record growth in per capita income as well as social indicators such as life expectancy and the UN Human Development Index.
- ❑ According to the World Bank study, moving from the bottom quartiles to the top quartile of 135 countries adds **2.3% to average annual economic growth** -- even after controlling for other growth factors such as education, civil conflict, investment, and income. (Djankov, McLiesh, Ramalho, 2006)

Improving Regulatory Quality Leads to Strong Macro Performance

Top Twenty Economies on the Ease of Doing Business Scale

1. Singapore
2. New Zealand
3. United States
4. Hong Kong, China
5. Denmark
6. United Kingdom
7. Ireland
8. Canada
9. Australia
10. Norway
11. Iceland
12. Japan
13. Thailand
14. Finland
15. Georgia
16. Saudi Arabia
17. Sweden
18. Bahrain
19. Belgium
20. Malaysia

2009 Doing Business Rankings for BRIC Countries and South Africa

- China 83
- Russia 120
- India 122
- Brazil 125

South Africa 32 (up 3 places from 2008)

Conclusions

- ❑ A firm and enduring commitment from the center of government is a necessary condition for a successful regulatory program.
- ❑ Accountability is required because special interests are especially powerful and benefits are diffused and lag political costs.
- ❑ An effective regulatory program should ensure that Regulatory Impact Analysis is of high quality and conducted to promote economic efficiency and fairness.
- ❑ Transparency and openness are necessary to maintain public support for a regulatory reform program.

References

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- ❑ **Federal Rulemaking Flowchart:** <http://reginfo.gov/Regmap/index.html>
- ❑ **Executive Order 12866 as amended, Regulatory Planning and Review** (September 30, 1993): <http://www.whitehouse.gov/omb/inforeg/eo12866.pdf>
- ❑ **Listing of regulations under Executive Order 12866 review:** www.whitehouse.gov/library/omb/OMBREGSP.htm
- ❑ **Listing of OIRA's meetings with outside parties on regulations under OMB review:** www.whitehouse.gov/omb/oira/meetings.html
- ❑ **2008 Report to Congress on the Costs and Benefits of Federal Regulations:** http://www.whitehouse.gov/omb/assets/information_and_regulatory_affairs/2008_cb_final.pdf
- ❑ **OMB guidance to agencies on Regulatory Analysis** (September 17, 2003): www.whitehouse.gov/omb/circulars/a004/a-4.pdf
- ❑ **OMB Bulletin for Agency Good Guidance Practices :** http://www.whitehouse.gov/omb/fedreg/2007/012507_good_guidance.pdf

Questions?

John F. Morrall III
jmorrall3@aol.com