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March 16, 2009

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Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget
Attn: Ms. Mabel Echols
Room 10102, NEOB
725 17th Street, N.W.
Washington, D.C. 20503

**Re: Comments on Federal Regulatory Review Process (74 Fed. Reg. 8819
(Feb. 26, 2009))**

Dear Ms. Echols:

We respectfully submit these comments on behalf of our Firm. Our clients participate in many different federal agency regulatory processes, including those relating to the environment, international trade, tax, food safety, consumer product safety, pharmaceuticals, fisheries, advertising and antitrust, telecommunications, animal welfare, and securities and finance. In summary, while the new Administration is sure to set its own substantive regulatory course, it has the very same interest as preceding administrations as far back as the 1970s in fostering a transparent and rigorous regulatory review process at the Office of Management and Budget ("OMB") and, more recently, the Office of Information and Regulatory Affairs ("OIRA"). We are encouraged by the President's interest in, and attention to, regulatory oversight and submit these comments with the hope that any future changes or executive orders be founded in the application and analysis of impartial standards to ensure that proposed regulations are appropriately coordinated and prioritized, efficiently implemented, and properly assessed to balance the direct and indirect cost and benefits.

Indeed, OMB and OIRA have traditionally been home to some of the federal government's most talented professionals. We are pleased that the President has continued this tradition by appointing and relying on well-regarded experts in regulatory review and analysis, such as Professor Cass Sunstein.

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I. COMMENTS

The request for comments identified several specific areas where OMB is seeking comments and recommendations. For sake of convenience, we address the subjects identified in OMB's request for comments in the order presented in the Federal Register.

A. The Relationship Between OIRA and the Agencies

OIRA's relationship with the agencies has certainly evolved since it was created under the Paperwork Reduction Act of 1980 to review proposed collections of information.¹ OIRA's place in the regulatory review process was confirmed by President Clinton in E.O. 12,866, which tasked OIRA with regulatory oversight and stated that OIRA "is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies,"²

Additionally, successive Congresses have seen fit to tap OIRA's expertise for other initiatives. The Congressional Review Act required OIRA to make determinations about whether a rule is "major."³ Under the Government Performance and Results Act, OIRA provides the President critical analysis of agency performance and other information necessary to prepare the annual budget.⁴ OIRA is also the President's tool to ensure that Regulatory Flexibility Act⁵ is faithfully executed by the agencies, and the Paperwork Reduction Act⁶ grants OIRA the authority and obligation to review and approve agency information collection activities in a rulemaking.

Since President Clinton signed E.O. 12,866 in 1993, each administration has heavily relied on OIRA to provide a rigorous and transparent regulatory review process. Such a process makes rules more effective and administration goals more attainable -- regardless of the policies advanced by any particular administration. Indeed, OIRA was created, not to advance any substantive policy goal, but to improve the process under which regulations are promulgated.

¹ When President Clinton signed the Paperwork Reduction Act of 1995, OIRA's information collection review role was expanded to include more types of information collected and disseminated by an increasingly large number of federal entities.

² E.O. 12,866 §2(b).

³ 5 U.S.C. §§ 801 *et seq.*

⁴ 31 U.S.C. §§ 1101 *et seq.*

⁵ 5 U.S.C. §§ 601 *et seq.*

⁶ 44 U.S.C. §§ 3501 *et seq.*

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As President Clinton wrote in E.O. 12,866:

With this Executive order, Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public.

Under this mandate, OIRA has provided a critical and dispassionate “second look” at agency rulemaking, sought to ensure that an administration is meeting its goals in an efficient and transparent manner, and served as an arbiter of individual rulemakings where impacts and jurisdiction are shared by more than one agency, or where multiple agency rulemakings impact a single industry sector. In its arbiter role, OIRA helps coordinate disparate agency efforts to ensure that a president’s agencies are acting in unison, avoiding redundancies, and ensuring that action by one agency does not work at cross purposes with another agency’s action. This role is especially important for a new administration – particularly one with an ambitious regulatory agenda requiring substantial efforts across the executive branch. Several current and anticipated regulations, such as climate change regulation, will require the coordinated effort of the many agencies who reasonably claim jurisdiction over the issue.

Similarly, OIRA’s arbiter role becomes important where different agencies are seeking to regulate a single sector of the economy. Individual agencies seeking to regulate a specific economic sector may be able to assess with some degree of accuracy the impacts of that regulation on the sector. However, regulations do not occur in a vacuum. There can be multiple agencies seeking to regulate a single economic sector, however, and only OIRA is in a position to analyze the cumulative impacts of multiple regulations on a single economic sector.

In addition to statutory obligations and its role as an interagency coordinator and facilitator, OIRA provides an independent forum to assess the need for regulation, the efficacy of regulation, the availability and feasibility of regulatory alternatives, and the impacts of regulation on the regulated community. These roles require a delicate balance of agency integration and independence.

From the perspective of OIRA integration into agency regulatory efforts, there is an important normative policy goal in enabling and even requiring agencies to consult with OIRA early in the rulemaking process, so that Administration priorities and analyses can inform the rulemaking before the agency becomes fully vested in any specific regulatory outcome. By working with an agency from the inception of the rulemaking process, instead of simply

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critiquing a near-final rule, OIRA can help an agency identify and assess the direct and indirect costs and benefits of all regulatory options before a single favored regulatory solution takes hold. Indeed, the analysis that OIRA can bring to bear at early stages of agency rulemaking can often help the agency identify lower-cost regulatory alternatives that provide equal or greater benefit.

Still, OIRA needs to remain independent from other agencies. Regulatory agencies are designed to regulate. They are adept at recognizing the incremental benefits of increasingly strict regulations, but often do not adequately consider the full costs of those regulations. Also, at both an institutional and individual human level, agencies can become vested in certain outcomes. OIRA was created to provide the agencies and the President with an independent, impartial, and unencumbered analysis of proposed agency actions.

An independent OIRA also is uniquely suited to help prevent conclusion-driven regulatory analyses. OIRA alone has the ability to step back from an agency rulemaking, view the entire field of executive branch efforts, and provide the President the ability to prioritize those efforts and focus on those regulations which provide maximum benefits when assessed with costs. Regulations typically require the dedication of government resources. Where the government's resources are limited, as they often are, there will necessarily be trade-offs. When trade-offs are required, OIRA has assisted the President in choosing the regulatory course with the greatest benefit.

In sum, OIRA has a long history of providing independent expertise to presidents. Its ability to be effective requires a balance between agency integration and independence. We hope that OIRA will maintain that balance and that this Administration will continue to use OIRA for its impartial analysis and ability to arbitrate agencies' differences to effectuate the President's priorities in the most efficient manner.

B. Disclosure and Transparency

Disclosure and transparency are critical components of any rulemaking. President Obama has noted that open processes not only preserve public confidence in the rulemaking process but also foster greater participation in the rulemaking process. Regulatory agencies act properly when they have investigated well the benefits, impacts, and potential detriments of a proposed action. Maintaining an open process that encourages stakeholder participation helps an agency generate the best available information on which to base its rules.

To that end, OMB has already significantly opened the rulemaking and regulatory oversight process. The creation of www.FirstGov.gov has made rulemaking information widely available and accessible to anyone with a computer. While providing information available on a website seems fundamental now, prior to the launch of FirstGov, stakeholders were forced to rely on document rooms – largely located in Washington, D.C. OMB and the agencies have

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moved dockets online, ensured that comments are public, and encouraged increased public participation in the rulemaking process by encouraging eRulemaking and the electronic submittal of comments.⁷

Consistent with E.O. 12,866, OIRA also takes significant steps to ensure the openness of its processes. OIRA makes publicly available inspection logs, meeting records, and communications with outside parties regarding rules under review. In this way, OIRA is significantly more transparent than any other federal agency, where meetings between agency heads and interest groups or organizations are not generally made public; and, unless a Freedom of Information Act request is granted and written government records of the meeting exist, such meetings would not ordinarily be disclosed.

Additionally, when peer review is needed for rules subject to Regulatory Impact Analysis (“RIA”), OMB recommends that: “(a) peer reviewers be selected primarily on the basis of necessary technical expertise; (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand; (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner. OIRA will be giving a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures.”⁸ Requiring peer review by independent and impartial experts, and requiring those experts to conduct their analysis in the light of day, helps ensure both a robust and credible peer review and analysis of the data, analyses, assumptions, and scientific methods on which rules are promulgated.

Following promulgation, OIRA makes available a wide variety of information reviewed by OIRA and relied upon by the promulgating agency. This information includes draft proposals, agency analyses, correspondence between OIRA and the agency, and correspondence OIRA receives from outside parties.

Implementation of these principles is not *ad hoc*. OMB developed extensive guidance and memoranda to ensure that principles of disclosure and transparency are met.⁹

⁷ Memorandum for the President’s Management Counsel, Re: Regulations.gov, Evans, Karen S., Graham, John D. (Mar. 1, 2004).

⁸ Memorandum for the President’s Management Counsel, Re: Presidential Review of Agency Rulemaking by OIRA, Graham, John D. (Sept. 20, 2001).

⁹ Memorandum for the President’s Management Council, Graham, John D. (Sept 20, 2001); Memorandum for Staff Re: OIRA Disclosure, Graham, John D. (Oct. 18, 2001).

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These existing principles are consistent with the current Administration's desire for a more open government. On March 9, 2009, President Obama issued a Memorandum for the Heads of Executive Departments and Agencies on steps to be taken to ensure the integrity of the science which underlies agency decision-making.¹⁰ In it, the President outlines transparency principles similar to those discussed here, including for the disclosure of all information forming the basis of the finding and use of an open and impartial peer review process to scrutinize the analysis.

C. Encouraging Public Participation in Regulatory Agency Processes

As stated in Section B above, we support the efforts to make agency rulemakings and the data which underlie these rulemakings more accessible to stakeholders. Strong, informed public participation is an important part of rulemaking and informed agency action.

Perhaps the most important step toward encouraging public participation in the agency rulemaking process is to ensure that the public is adequately informed of ongoing rulemakings in which they have an interest. OMB has already made great strides toward breaking down the barriers which traditionally made rulemaking participation an "inside the Beltway" exercise. For instance, Firstgov.gov and regulations.gov provide everyone with direct online access to every docket document relied upon in an agency rulemaking and, with minor exceptions due to sensitive information or trade secrets, every comment submitted to the docket. These mechanisms provide the average citizen with the same tools as those who are consistently active in the regulatory process for tracking and performing an informed analysis of a rulemaking which may impact him or her. Moreover, robust key-word search tools provide those who do not pore over the Federal Register an easy way to identify issues which may impact them. Additionally, eRulemaking allows everyone to submit comments to agency rulemakings from any computer and at no cost. The best indicator of the efficacy of these efforts is the increase in public comments to agency rulemaking. Indeed, agencies can now expect up to several hundred thousand comments (mostly electronic) on major rulemakings.

The best way to encourage public participation in the agency rulemaking process is to provide the public easy access to rulemaking information and to provide an easy means of commenting on rulemakings. We believe that existing access enhancements effectively meet the goals of public participation.

¹⁰ Memorandum for the Heads of Executive Departments and Agencies, Re: Scientific Integrity (Mar 9, 2009).

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D. The Role of Cost-Benefit Analysis

The cost-benefit analysis has been used by OMB and OIRA to support administration goals in many different ways, and through successive administrations. Critics dismiss the cost-benefit analysis as a means of monetizing harms and risks and assigning prices to human lives, environmental impacts, and other intangibles. These critics fail to understand – or at least fail to acknowledge – that rigorous cost-benefit analysis makes regulations stronger and helps any administration identify, prioritize, and expedite those rules that have the potential to deliver the greatest benefit most efficiently.

The goal of regulatory agencies is to regulate. These agencies' inclination, therefore, is to examine and recognize (sometimes to the point of overstating) the incremental benefits of increasingly strict regulations, but not necessarily the cost of those regulations on the regulated community or on government resources. When true costs are not accurately factored into the analysis of an agency rule, incremental beneficial gains alone drive decision-making. However, promulgating the most strict regulation possible can often work against a rule's intent or create new and unanticipated problems in other areas. Certainly, there is a tipping point where overly-strict regulation can be counterproductive.

Professor Cass Sunstein points out several examples in an article entitled *Your Money or Your Life*.¹¹ Consider, for example, an extremely strict carbon monoxide regulation for motor vehicles. Car companies may attempt to make cars lighter (and therefore more fuel efficient) in order to meet the new standards. However, by reducing the structural support in the vehicle, passengers may be less protected than before the standards. Even if cars remained equally safe, the resulting price increases for compliant vehicles may cause consumers to opt against buying a new car – and continue to drive their older (higher-emitting) vehicle.

Rigorous analyses assessing benefits and costs can thus also help identify the behavioral tipping points where increasingly strict rules begin to work against their intended purposes. Identifying these decisional junctures helps agencies create rules that provide maximum benefits (e.g., regulating emissions while preserving a domestic industry; requiring a safety feature without consumers deselecting the product; or producing a food safety regulation while keeping food affordable for working families).

Sometimes, maximum net benefits are achieved through regulatory alternatives that are able to impose lesser costs to achieve the same or greater benefits. Again, rigorous cost-benefit analyses are the means by which the need for alternatives is realized and the efficacy of alternatives is judged. Without requiring a calibration of costs and benefits, and establishing a structure through an agency such as OIRA to ensure some consistency and quality of analysis,

¹¹ *Your Money Or Your Life*, Sunstein, Cass R., The New Republic (Mar. 15, 2004)

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regulatory agencies would less often (if not rarely) seek out alternatives and efficient means of minimizing costs.

More broadly, cost benefit analyses assist an administration with agenda setting and prioritizing. President Obama has set ambitious goals for his Administration. Each regulatory agency has a part to play in implementing the President's agenda, and every regulatory action requires the commitment of government resources. However, these resources are not limitless, and trade-offs will inevitably become necessary. An administration cannot make every item on its agenda a number one priority. When evaluating trade-offs, this Administration should ensure that it has strong analytical tools and analyses available to assist it to make rational and informed decisions about how to employ its resources and political capital, in the interests of achieving the maximum net benefit for the nation.

For its part, OMB has, through the years and successive administrations, developed solid analytical models and approaches for agencies to follow. While this Administration may see fit to refine the OMB protocols for these analyses, that is far different from abandoning or minimizing to the point of irrelevance these valuable tools. Individual regulatory agencies are simply not equipped or inclined to provide this dispassionate analysis due to their individual statutory mandates, natural bias toward their own initiatives, and, often, lack of knowledge about the initiatives of other agencies. OIRA ensures rigorous and transparent analyses will be performed, beyond the reach of political pressures or agency turf wars. A president equipped with a fulsome understanding of the relative costs and benefits of each regulatory initiative competing for finite resources has the ability to prioritize and coordinate interagency efforts to triage those rules that can deliver the maximum net benefits.

In addition to helping the President rank his *existing* regulatory priorities, rigorous cost-benefit analyses have actually helped administrations identify *new* regulatory programs that promise to provide maximum net benefits. When OIRA analyses have identified potential initiatives where benefits far exceed costs, OIRA has sent "prompt letters" to agencies suggesting how they can improve their regulations or requesting that changes to a regulation be expedited. "A prompt letter in 2002 helps account for the government's 2003 decision to require companies to disclose levels of trans fatty acids among their 'nutrition facts' – a decision that is expected to save hundreds of lives each year."¹²

In sum, OIRA's cost-benefit analyses are tools - tools which favor no political ideology nor party platform. Instead, rigorous, consistent assessment and comparison of costs and benefits provides each administration with the knowledge and means to help effectively implement its own agenda. Cost-benefit analyses merely inform the decision-making of administrations; they do not make the decisions. Certainly, each administration has its own regulatory priorities, and

¹² *Your Money Or Your Life*, Sunstein, Cass R., The New Republic (Mar. 15, 2004).

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considerations that it might wish to elevate in a regulatory review process, including a more refined consideration of behavioral responses to regulation. There are, moreover, different and evolving techniques to measure costs and benefits. We are sure this Administration will refine the already well-developed OIRA and OMB regulatory protocols to fit its collective view of how best cost-benefit analyses should be conducted. These analytical tools are important to maintain and to employ, and should not be scrapped or diminished. Rather, President Obama should use these tools, appropriately refined, to make his agencies' rules more effective, to identify regulatory alternatives, and to set and rank his competing priorities to deliver maximum net benefits.

E. The Role of Distributional Considerations, Fairness, and Concern for the Interests of Future Generations

An effective regulatory review can help identify impacts that may unduly burden certain segments of society, as well as costs and benefits which may only be realized by future generations. OMB recognizes that "[t]hose who bear the costs of a regulation and those who enjoy its benefits often are not the same people."¹³ OMB Circular A-4 provides detailed guidance on how specifically to capture data on these distributional effects and incorporate them into the analysis. Additionally, under President Clinton's Executive Order 12,898, OMB participates in the Interagency Working Group on Environmental Justice.¹⁴ This working group is charged with collecting and analyzing data to better understand, account for, and respond to environmental impacts which disproportionately affect poor or minority populations.

Future costs, benefits, and impacts are most difficult to measure in a fair and accurate manner. Proponents of the precautionary principle would argue that attempts to measure future impacts are improper because such measurements require difficult estimates and have the potential to underestimate, or discount, risks or benefits to future generations. Instead, precautionary principle proponents would suggest the government regulate future risks with an adequate margin of safety based solely on speculative potential impacts and attending to worst-case scenarios. However, precautionary principles have significant potential to become an undisciplined – or at least an analytically vacant – way to justify *any* government action. Certainly, the government in general has wide latitude to regulate many and various actual or anticipated risks or harms. However, increasingly strict regulations are typically met with increasingly high costs. These precautionary principle proponents fail to understand that there is a tipping point when costs can greatly exceed benefits and the intent of the regulation is countermanded or new, different risks and detriments are created.

¹³ OMB Circular A-4, at 14.

¹⁴ E.O. 12,898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (Feb 11, 1994).

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Future impacts, like present day impacts, should be measured according to consistent, reasonably empirical, transparent standards. These analyses also assist an administration in prioritizing its efforts. If an administration seeks to prioritize its goals through use of the precautionary principle, every initiative becomes the number one priority, and the most effective regulatory initiatives remain unidentified, under-funded, and can be asphyxiated by less effective competing proposals. A proper assessment of future costs and benefits can help the President put the weight of his efforts behind those regulatory proposals that are most likely to provide the greatest present and future benefits.

Finally, any attempt to conduct such analyses requires estimation and, as OMB instructs, ample use of best professional judgment. We support efforts to improve these analyses, including by providing for transparent peer review. We encourage the Administration to work with stakeholders to improve analytical techniques. Opting against measuring that which is difficult to measure is not the answer.

F. Methods of Ensuring that Regulatory Review Does not Produce Undue Delay

One of the most common criticisms of the OMB regulatory review process is that it delays promulgation of important rulemakings. Some argue that it has been used intentionally to tie up certain rulemakings. For the reasons explained above, we support regulatory review for the impartial, dispassionate, quantitative and qualitative analysis it provides. Sometimes the regulatory review process will and should reveal certain initiatives as bad ideas that either should not be pursued or must be extensively reconsidered, but this differs from delay for delay's sake. Effective regulatory review should be a catalyst for quality, effective regulatory efforts – not an impediment.

That being said, we do not believe that comprehensive regulatory assessments should be sacrificed for mere expediency. Regulatory review should be considered as much a part of the rulemaking process as notice and comment. If the Administration finds that the regulatory review period is too long, we propose that the Administration fully equip OMB and OIRA to conduct a prompt review that does not sacrifice sound analysis. We support an increase in funding for OMB and OIRA so that these groups can provide an effective analysis within a reasonable time period. Additionally, OMB and, in particular, OIRA, should be substantively involved in an agency rulemaking from the inception. Early action can provide needed coordination among other agencies and the regulated community. Indeed, OIRA involvement can help agencies anticipate and address OIRA recommendations and concerns, before the eleventh hour. Such an action would provide the Administration with timely information necessary to direct or fine tune agency action before an agency becomes fully vested in the proposal. Such efforts also help to better inform the public dialogue. If the regulatory review process is to be “reformed,” one outcome should be to ensure that OMB and OIRA are involved

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more effectively earlier in the regulatory process. Such a step may alone help ensure that OMB's pre-promulgation review can proceed effectively and efficiently.

In sum, we believe that regulatory review should proceed as expeditiously as possible – but not be used merely to stall regulation. However, comprehensive regulatory review should not be sacrificed for the sake of expediency. If the Administration is determined to speed up the regulatory review process, we ask that it give OMB and OIRA the funds, personnel, and resources, as well as the early access, necessary to accomplish that task.

G. The Best Tools for Achieving Public Goals Through the Regulatory Process

All administrations are faced with myriad goals and opportunities which require coordination, prioritization, and analysis necessary to direct resources toward those initiatives that will provide the maximum benefit with minimal cost. President Obama has already identified numerous policy objectives that will be implemented by regulatory actions across executive agencies. With a large number of regulators, each eager to tackle the problems within their respective area, it is critical that the President maintain his own executive supervision via OMB and OIRA, to ensure that presidential objectives are being efficiently pursued through coordinated agency effort, and that one agency's efforts do not undo another's or compound the burdens on a single economic sector. As discussed more fully above, OMB and OIRA have ably served past presidents in meeting these goals.

A rigorous regulatory review process through OMB and OIRA also is a critical tool for achieving those public goals imparted to the President by his electorate. Accomplishing multiple public goals with finite resources necessitates rigorous analysis and calibration of benefits and costs to ensure that the Administration returns the maximum potential benefit per expended resource.

Transparent and accessible rulemaking processes are also key. The best rules are born of the most informed rulemakings. Requiring peer review, disclosure of contacts, and open dockets provides all of us the assurance that decisions which impact our lives are made in the light of day. Easy and accessible rulemaking data and the ability to submit electronic comments with a few keystrokes allows everyone the opportunity to provide their government with an informed opinion on the rules which impact them.

In sum, consistency with presidential objectives, efficient use of government resources through rigorous analysis, increased transparency and public participation are the best tools for achieving public goals through the regulatory process. Significantly, many statutory mandates and the directives of prior administrations have provided these tools to the President. We therefore encourage this Administration to build on the successes of preceding administrations and not seek to replace them entirely.

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II. CONCLUSION

We appreciate the opportunity to provide comment on the President's administration and management of the regulatory review process. Indeed, the President's interest in taking comments on these issues speaks well to his interest in proper regulatory review, as well as his interest in increasing public involvement in government.

We support the President's vision of a regulatory review process that is open, transparent, and accessible, and encourage the President to look to existing efforts to further those goals. We also support the President's interest in comprehensive and fulsome regulatory review. We encourage the President to empower OMB and OIRA by ensuring it has the funds and resources necessary to conduct efficiently those analyses that provide a foundation for sound and structured decision-making on regulatory initiatives. Indeed, these analyses can be improved, particularly when they attempt to measure that which is difficult to measure. But, these analyses remain do critical. They make rules more effective and protective, identify lower-cost alternatives, coordinate agency efforts, and allow the President to effectively execute his priorities.

If you have any questions, please feel free to contact me at [REDACTED] or [REDACTED]

Sincerely,



David E. Frulla
Wayne D'Angelo