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***“Government Capacities to Assure High Quality  
Regulation”***

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STATEMENT OF JEFFERSON B. HILL  
AT THE  
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I have been invited today to discuss ways to improve the quality of regulations issued by regulatory agencies – those national administrative bodies responsible for strengthening health care, protecting the environment, enforcing safety requirements, providing a sound financial system, and administering other national services. I will summarize basic concepts and tools for improving regulatory quality recommended by the OECD and how these have been implemented in the United States of America.

Before I start, I would like to clarify what I mean by a “regulation.” In America, the Congress enacts laws, which authorize or direct a Federal Executive branch regulatory agency to carry out specific responsibilities. Each agency, acting within the scope of the laws applicable to it, may itself issue a “regulation” which will set requirements for individuals, businesses, and other private institutions, which the agency can enforce, either administratively or in Federal court, in specific ways. In my discussion, I am referring to the “regulations” issued by Federal Executive branch regulatory agencies, not to the “laws” enacted by the Congress.

FRAMEWORK FOR IMPROVING AND REFORMING REGULATIONS

In 1997, OECD recommended that countries “*adopt at the political level broad programs of regulatory reform that establish clear objectives and frameworks for implementation.*” To give meaning to this concept of a “*framework,*” OECD specifically recommended that governments “*create effective and credible mechanisms inside the government for managing and coordinating regulation and its reform.*” These OECD recommendations include three basic elements: (1) national political support, (2) a public statement of national policies on regulatory quality; and (3) establishment of an administrative framework – designation of a government agency or specific government staff responsible for improving and reforming regulations issued by Federal Executive branch agencies.

Regulations are statements of policy directed toward the public, enforceable either administratively or in court. As such, regulations are one of the ways that the leaders of a national agency communicate with the public, and embody the political policies of the national government. To assure that regulations are only issued when necessary, and, when issued, meet the standards that the national leadership desires, requires sustained and consistent political leadership, starting at the top.

A statement from the national political leadership of national regulatory improvement policy is critically important. A statement of clear policy objectives creates a basis by which to hold government officials accountable, facilitates coordination between Federal agencies and across regional jurisdictions, and, by making the national regulatory quality goals transparent, enhances the credibility of the national effort both with agency staff and with the public, thus speeding up results.

In addition, there has to be an effective and credible mechanism inside the government for promoting, coordinating, and tracking regulatory quality reforms. To maintain consistency of regulatory policy and systematic approaches to assure regulatory quality across the whole range of national agencies requires systematic oversight.

Specifically, achieving regulatory quality requires the allocation of specific responsibilities and powers to an agency or a component of an agency at the center of government representing directly the government's leadership to monitor and promote progress across the whole of government. The effectiveness of the center organization's monitoring, coordination, and management functions is enhanced by its being directly linked to the center of political and administrative authority. But I want to stress that, even with central oversight, the primary responsibility for achieving regulatory quality must be at the regulatory agency itself. That is where the detailed information and specialized expertise lies and where specific regulatory policies are developed.

What is the framework that we have established in America? Starting in 1971, every American President has taken steps or issued Executive Orders to improve the quality of national regulation. They have issued Executive Orders (i.e., executive decrees) to Federal Executive branch agencies, worked directly with the leadership of Federal Executive branch agencies and, as necessary, with the Congress. In 1981, the President signed a law that created the Office of Information of Regulatory Affairs (OIRA) as a part of the U.S. Office of Management and Budget (the central management and budgeting institution located in the Executive Office of the President). The President also issued an Executive Order to have OIRA provide central -- in our case, presidential -- oversight of the regulations issued by many of the Federal Executive branch agencies.

Currently, we carry out our central regulatory oversight under Executive Order 12866, issued by President Clinton in September 1993. I also refer you to the 20 September 2001, memorandum from Dr. John D. Graham, Administrator of the Office of Information and Regulatory Affairs (OIRA), entitled "Presidential Review of Agency Rulemaking by OIRA." This memorandum gives a detailed description of how OIRA carries out regulatory review, summarizing the principles we follow and the procedures we use. Copies are available at this seminar. A copy of Executive Order 12866 is also available at "[http://www.nara.gov/fedreg/executive\\_orders\\_pdf/eo12866.pdf](http://www.nara.gov/fedreg/executive_orders_pdf/eo12866.pdf)" and Mr. Graham's memorandum is available at OIRA's Internet website, "<http://www.whitehouse.gov/omb/inforeg/regpol.html>."

The President on the basis of his executive authority establishes regulatory policies. Executive Order 12866 requires that agencies promulgate "... only such regulations as are required by law, are necessary to interpret the law or are made necessary by compelling public need ... ." In addition, the Order calls on regulatory agencies, in developing a regulation, to –

-- Identify the problem to be solved and assess its significance;

- Identify and assess alternatives to direct regulation, including economic incentives and information, and use performance standards to the extent possible if regulation is chosen;
- Set priorities by considering the degree and nature of risks from different sources;
- Regulate only upon a reasoned determination that benefits justify costs;
- Base decisions on best, reasonably obtainable information on the need for and consequences of regulation;
- Avoid regulations that are inconsistent or duplicative of other regulations;
- Draft regulations that are simple and easy to understand.

The Office of Information and Regulatory Affairs (OIRA) conducts day-to-day centralized regulatory oversight and quality management. The role of OIRA is to review the regulations and impact analyses to identify decisions and policies that are not consistent with law, the President's regulatory policies, principles, and priorities; to coordinate among agencies; to discuss any inconsistencies with the regulators; to suggest alternatives; and to enforce agency compliance with the regulatory principles and review procedures stated in Executive Order 12866.

OIRA reviews the more important agency regulations three times: (1) at the planning stage in the agency during preparation of the semi-annual "Unified Agenda of Federal Regulatory and Deregulatory Actions;" (2) at the proposed stage before they are published for public comment in the national gazette (the "Federal Register"); and (3) at the final stage before publication in the "Federal Register" as a finished regulation that will be binding on the public. The first review is cursory, involving an overview of planned regulations to determine if any can be expected to raise unexpected problems. The second and third reviews are rigorous, particularly for the more important regulations. In the past few years, OIRA has reviewed roughly 600 significant proposed or final regulations a year. Regulatory agencies issue roughly 4500 final regulations a year. The requirement that agencies competently perform regulatory impact analyses, and the authority OIRA has to review them, is critical to the success of this enterprise.

## TOOLS TO RAISE REGULATORY EFFICIENCY AND EFFECTIVENESS

1. Regulatory Impact Analysis. In 1997, OECD recommended that governments "*establish principles of 'good regulation' to guide reform \* \* \* [and] integrate regulatory impact analysis into the development, review, and reform of regulations.*" Specifically, OECD recommended as a key principle that regulations should "*produce benefits that justify costs, considering the distribution of effects across society.*"

Regulatory Impact Analysis serves a number of goals. A Regulatory Impact Analysis attempts to widen and clarify the relevant factors for decision-making at the regulatory agency. It implicitly broadens the mission of regulators from highly focused problem solving to balanced decisions that trade off solutions to specific problems against wider economic and distributional goals. It is important to note that a Regulatory Impact Analysis does not itself predetermine the

proper course of action for an agency decision-maker. Rather, the value of a Regulatory Impact Analysis lies in the analysis of the potential consequences of a regulation – questioning the stated rationale, understanding real-world impacts, exploring assumptions.

In America, the first presidential endorsement of Regulatory Impact Analysis occurred in 1974. A 1981 Executive Order substantially strengthened the requirements for a Regulatory Impact Analysis, a requirement that has continued, in basic form, to this day. Presidential use of the Executive Order assures that regulatory agencies accept accountability for compliance.

Specifically, Executive Order 12866 states that, “in choosing among alternative regulatory approaches, [Federal] agencies should select those approaches that maximize net benefits ... .” The Order further states that, “Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” In addition, regulatory agencies must prepare a Regulatory Impact Analysis of each important proposed regulation – those with an estimated impact of \$100,000,000 a year. In the Regulatory Impact Analysis, the regulatory agency is to demonstrate that the benefits of the regulation justify its costs and that the agency has selected the most cost-efficient approach to resolving the problem. A Regulatory Impact Analysis is prepared by the regulatory agency, and OIRA provides quality assurance. There are roughly 40 such important regulations issued in final form each year.

The Executive Orders have allocated responsibilities for Regulatory Impact Analysis carefully. Having the regulatory agency draft the Regulatory Impact Analysis creates a sense of institutional “ownership” and facilitates integration of the Regulatory Impact Analysis into agency decision-making.

OIRA oversees the Regulatory Impact Analysis process and seeks to ensure consistency, credibility, and quality of agency analytic efforts. OIRA has also issued guidance to the Federal agencies on how to prepare a Regulatory Impact Analysis (see OIRA’s Internet website at “<http://www.whitehouse.gov/omb/inforeg/riaguide.html>” and, for a follow-up memorandum, see “<http://www.whitehouse.gov/omb/memoranda/m00-08.pdf>”). In addition, OIRA has sought to target agency efforts to draft a Regulatory Impact Analysis where the potential impacts of a regulation are largest, and where the prospects are the best for the Analysis to influence the regulatory decision-making process. (For access to copies of our recent annual Reports to Congress on the Costs and Benefits of Federal Regulations -- reports that summarize many Regulatory Impact Analyses, see OIRA’s Internet website at “<http://www.whitehouse.gov/omb/inforeg/regpol.html>”).

Regulatory Impact Analysis is also fully integrated into the public consultation process. Under Executive Order 12866, an agency’s Regulatory Impact Analysis is to be released to the public at both the proposed and final stages of rulemaking as part of the notice-and-comment process, allowing all interested members of the public to comment on the assumptions and results of the Analysis. OIRA has found that the assumptions and data used in a Regulatory Impact Analysis can be improved if they are tested through public disclosure and consultation.

2. Assessment of regulatory alternatives. OECD has found that command-and-control regulations have traditionally been the first choices for most governments, offering predictability about what is required, providing measures for enforcement, and generating a degree of predictability of outcome. However, command-and-control regulations rely on coercion and penalties to effect change, and thus tend to be adversarial, which can result in lower than desired compliance. OECD has also found that regulatory alternatives that focus on encouraging desired behavior rather than discouraging undesired behavior may, depending on circumstances, be more effective in accomplishing the agency's regulatory goals.

One particular alternative to a command-and-control regulation relied upon in America is performance-based regulation. Executive Order 12866 explicitly states that "Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt." Performance-based regulations specify desired outcomes or objectives to be achieved rather than the means by which the outcomes or objectives must be achieved. This allows companies to choose the process by which they will comply with the law. A performance-based regulation allows efficient and lower cost processes to be used, promotes innovation, and the adoption of new technology, and focuses on results or outputs rather than inputs.

3. Reducing the burden of permits and licenses on business. In 1997, OECD recommended that "*Reducing red tape and government formalities can produce substantial payoffs in government efficiency and economic cost-savings.*" OECD explained that "*Reducing the operating and dynamic costs of ex ante permissions and licenses is a high priority for governments that wish to increase business start-ups and improve competitive pressures throughout the economy.*" Ex ante permissions and licenses increase investment delays and uncertainties, have disproportionate effects impeding the start-up of small businesses, and are very costly for public administrations to apply.

In America, the permitting and licensing of business tends to be a matter for State and local governments, not the Federal government. Even so, the Federal government does carry out such permitting and licensing, particularly if clear health, safety, or environmental risks may be involved. Recent efforts to reduce burden for permits and licenses involve standardizing of permits and the simplification of the application process made possible by advances in information technology. For example, for an environmental program regulating the storage of hazardous waste, a Federal agency is developing a standardized permit which a business could obtain, without having to undergo site-specific evaluations or individual permit negotiations, if the business could show that it had storage units that met designated minimum design and management criteria. Another Federal agency has established a permitting system for Atlantic tuna fish, available through the Internet, which is much faster and more accurate than the previous permitting system. Similarly, a Federal agency has established a free service for the submission through the Internet of license applications for export permits.

## TOOLS TO IMPROVE TRANSPARENCY AND ACCOUNTABILITY

In 1997, OECD recommended that governments: "*Ensure that regulations and regulatory processes are transparent, non-discriminatory and efficiently applied.*" By "transparency,"

OECD means “*the capacity of regulated entities to express views on, identify, and understand their obligations under the rule of law.*”

Regulatory transparency has powerful upstream and downstream effects in the regulatory policy-making process. Transparency encourages the development of better policy options, and helps reduce the incidence and impact of arbitrary decisions in regulatory implementation. Transparency improves regulatory quality and the public sense of fairness by having the government collect information more interactively from a wider range of interests.

Transparency improves regulatory management through facilitating implementation and improving public compliance. Those who have to comply need to understand what they are supposed to do. This may require positive assistance from the government in explaining the regulatory requirements and directly suggesting ways to achieve compliance. In addition, those who benefit from a new regulatory program also have to know of the new regulation so that they can evaluate what has been accomplished by the regulatory program and suggest ways further to improve it.

1. Government consultation with interested parties. In 1995, OECD pointed out that: *“Consultation and public participation in regulatory decision-making have been found to contribute to regulatory quality by (i) bringing into the discussion the expertise, perspectives, and ideas for alternative actions of those directly affected; (ii) helping regulators to balance opposing interests; (iii) identifying unintended effects and practical problems; (iv) providing a quality check on the administration’s assessment of costs and benefits; and (v) identifying interactions between regulations from various parts of government.”* Tools for public consultation include informal consultation; circulation of regulatory proposals to selected interests for public comment; public notice-and-comment; and hearings.

Regulatory agencies in the USA use all of these tools. The tool most used is public notice-and-comment.

(a) Public notice-and-comment is more open and, assuming the public voluntarily participates, more inclusive than other tools. Regulatory agencies can receive needed information, particularly where their knowledge of affected parties is limited. The openness and formality of notice-and-comment procedures allows regulatory agencies and policymakers greater confidence that significant views have been heard. Public notice-and-comment increases the quality and legitimacy of policy by opening the policy-making process to a broader population.

In America, the formal notice-and-comment procedure that was first codified into law in 1946 forms the basis for a wide and comprehensive consultation process. Under the Administrative Procedure Act, a notice is published in the national gazette (the “Federal Register”) that includes the text or substance of the proposed regulation, and an introduction that explains the agency’s reasons for proposing to issue the regulation. All interested persons -- nationals and non-nationals alike -- have opportunity to participate by providing written data, views, or arguments. As Federal courts have interpreted the Administrative Procedure Act, public comments are maintained in a formal record; the regulatory agency must give public comments due consideration prior to adoption of the final regulation; and the regulatory agency is not permitted to rely on factual information not contained in the public record. The rulemaking agency publishes the text of the final rulemaking in the “Federal Register” at least 30 days before the effective date of the regulation, to give warning to those who have to comply what they have to do.

In America, trade associations, public interest groups, other institutions, and many individuals routinely monitor the “Federal Register” for proposed regulations that may affect them, and are prepared to submit public comments. Depending on the importance of the regulation, a regulatory agency may receive tens of thousands of public comments.

(b) A hearing is a public meeting on a particular regulatory proposal at which interested parties and groups can comment in person. In America, a hearing is announced in the “Federal Register” and scheduled during the public notice-and-comment period as needed.

2. Regulatory clarity, communication, and access. In 1997, OECD emphasized the need to improve the openness and enforcement of regulation: *“The content of regulations is important, but just as important is the accessibility and application of regulations.”* Making regulations easier to understand, and more readily accessible to those who have to comply is designed to combat growing regulatory complexity, fragmentation, inconsistency, unreadability, and problems with simply identifying what the relevant regulations are. Tools for regulatory clarity, communication, and access are comprehensive regulatory registers, plain language drafting, publication of future plans to regulate, electronic dissemination of regulatory documents, improving due process and administrative certainty, and appeals processes that are clear, predictable, and consistent.

(a) Comprehensive regulatory registers. In 1997, OECD recommended that governments *“create and update on a continuing basis public registries of regulations and business formalities, or use other means of ensuring that domestic and foreign businesses can easily identify all requirements applicable to them.”*

In America, once a regulation is adopted, it is easily accessible to affected entities. To become effective, final regulations must be published in the daily “Federal Register,” which is also available on-line (at “<http://www.nara.gov/fedreg/>”) . Most final regulations are indexed and published in the consolidated “Code of Federal Regulations,” which is also available on-line and updated annually (at “<http://www.gpo.gov/nara/cfr/index.html>”). The “Code” is a compendium of the regulations in force at a given time. Publication of a regulation in either of these national gazettes means, as a matter of American law, that the public is aware of its obligation to comply.

(b) Plain language drafting. In 1995, OECD explained the need for plain language in drafting: *“Regulators should assess whether regulations will be understood by likely users, and to that end should take steps to ensure that the text and structure of regulations are as clear as possible.”* OECD explained that: *“Clear and precise language reduces the costs of learning about regulations, minimizes disputes during implementation, and improves compliance.”*

In America, Executive Order 12044, issued in March 1978, declared that “Regulations shall be as simple and clear as possible.” Executive Order 12866 states that “Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.” This “simplicity and clarity” policy was reinforced in June 1998 through a presidential instruction to civil servants to write all documents “in plain language.”

(c) Publication of future plans to regulate. OECD has found that national publication of proposed future regulation is a rapidly developing strategy for improving transparency. The participation of interested parties in dialogue on proposed regulations is fostered as early as possible in the process, thus improving the likely quality of subsequent consultations.

In America, the “Unified Agenda of Federal Regulatory and Deregulatory Actions,” published twice yearly in the “Federal Register,” contains outlines of regulatory proposals, or plans, covering the entire administration and includes detail on the regulation’s priority, its impact on small businesses and other levels of government, and a timetable for planned action, as well as updates of updated information on regulatory proposals, or plans, that were previously described. (To search the content of the Unified Agendas issued since 1994 in the Internet, go to “[http://www.access.gpo.gov/su\\_docs/aces/aaces002.html](http://www.access.gpo.gov/su_docs/aces/aaces002.html)”).

(d) Electronic dissemination of regulatory documents. Advances in information technology, in particular improved data storage and the rapid development of the Internet, have provided major opportunities to improve the dissemination of regulatory material, thus enhancing regulatory transparency.

In America, increasing use of the Internet provides linkages and research capacities, and user-friendly electronic one-stop shops. The daily and the annual consolidated national gazettes, the “Federal Register” and the “Code of Federal Regulations,” are available, free of charge, on the Internet. The electronic one-stop shop link “<http://www.business.gov/>” provides practical assistance to businesses through answers to frequently asked questions, search capacities for Federal information, browsers for Government documents, and viewing of business-related items from Federal agencies.

Dissemination of information in this way typically knows no borders and access to online information is unrestricted and free of charge. Extensive American use of the Internet across a wide range of government agencies can be a powerful tool in enhancing the transparency of regulatory processes and regulations worldwide.

(e) Improving due process and administrative certainty. OECD has issued a number of reports stressing the importance of controls on agency regulatory discretion that are established through standardized, transparent procedures for making, implementing, and changing regulations.

Transparent and consistent processes for making, implementing, and revising regulations are fundamental to ensuring public confidence in the regulatory process and safeguarding opportunities to participate. Objective criteria for agencies to follow in making administrative decisions, and established procedures for when and in what ways to document these decisions can build needed controls around the exercise of regulatory discretion. Regulating the exercise of regulatory discretion helps assure greater consistency and fairness in managing regulations. Moreover, national adoption of an administrative procedure law controls excessive administrative discretion, improves the orderliness of administrative decision-making, defines the rights of citizens more clearly, and details standard procedures for making, implementing, enforcing, and revising regulation.

In America, the cornerstone of the regulatory system is the 1946 Administrative Procedure Act, which established the legal right of citizens to participate in rulemaking activities of the government on the principle of open access to all. (To find the Administrative Procedure Act in its current form, search for title 5, sections 551-559 at “<http://www4.law.cornell.edu/uscode/>”).

(f) Appeals processes that are clear, predictable, and consistent. In 1997, OECD recommends that governments: “*ensure that procedures for applying regulations ... contain an appeals process ...*.” Transparent and impartial appeals processes require the possibility of recourse to an agency – whether administrative or judicial – independent of the original decision-maker. Providing an appeal to an impartial body protects from arbitrariness, favoritism, and corruption, supports compliance with concepts of regulatory quality, and enhances the legitimacy of government regulation.

In America, the 1946 Administrative Procedure Act sets out criteria for a private party to object in Federal court to regulations and regulatory orders and appealing against their application. (To find the Administrative Procedure Act in its current form, search for title 5, section 706 at “<http://www4.law.cornell.edu/uscode/>”.) In addition, regulatory agencies have internal procedures establishing administrative appeal rights.

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In conclusion, in America, we have established a framework for improving and reforming regulations, and have adopted many of the tools recommended by the OECD to raise regulatory efficiency and effectiveness and to improve transparency and accountability. I do not want to suggest that this framework and these tools work perfectly and I am positive there is room for improvement. But they have brought success and have served to raise the quality of regulations issued by Federal Executive branch regulatory agencies. I will be pleased to discuss any of these efforts in greater detail as you may request.

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