HDMA
Healthcare Distribution Management Association

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

Re: Federal Regulatory Review: Request for Comment, 74 Fed. Reg. 8819 (Feb. 26, 2009) and 74 Fed. Reg. 11383 (Mar. 17, 2009).

Dear Sir or Madam:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments to the Office of Management and Budget (OMB) regarding the January 30, 2009 Memorandum from the President.[1] OMB has been directed to produce recommendations on Federal Regulatory Review and has now solicited comment on the issue. HDMA is pleased to offer its views on the important role that OMB has played in the federal regulatory process.

HDMA represents primary, full-service healthcare distributors. Each business day, HDMA member companies deliver more than eight million prescription medicines and healthcare products to more than 145,000 pharmacies, hospitals, nursing homes, clinics, physician offices, government and other providers in all 50 states. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system nearly $32 billion each year. For more information, please visit www.HealthcareDistribution.org.

HDMA offers these comments in the hope that they will facilitate constructive revisions to Executive Order 12866 (EO 12866 or Executive Order) and in addressing the vital role that OMB plays in the federal rulemaking process.

HDMA's comments can be summarized as follows:

[1] 74 Fed. Reg. 8819 (Feb. 26, 2009) and 74 Fed. Reg. 11383 (Mar. 17, 2009).

- HDMA strongly supports the OMB review process and believes that the OMB review of agency regulatory initiatives, including proposed and final rules, draft and final guidances and agency policy statements should continue.
- HDMA supports including specific elements of EO 12866 in a revised Executive Order:
  - The *Principles of Regulation* contained in Section 1(b), and
  - The requirement for performing a cost-benefit analysis.
- HDMA recommends that OMB reexamine, refine and update the definition of "significant regulatory action," and therefore, when a cost-benefit analysis should be performed.

HDMA STRONGLY SUPPORTS THE OMB REVIEW PROCESS

HDMA's members operate in a highly regulated environment. Healthcare product distributors occupy the middle space between pharmaceutical and medical device manufacturers and healthcare facilities, including pharmacies, physician offices, hospitals, long term healthcare facilities, clinics, and other entities that provide medical care to the public.

Our members purchase and distribute highly regulated products, including prescription and over-the-counter drugs, medical devices, medical and surgical supplies and equipment, chemotherapy and radiological agents, controlled substances, temperature-sensitive biological agents, vaccines, and products that have flammable, reactive, and other hazardous properties. As a consequence, our members, every day, must address the laws, regulations, policies, guidances, and other regulatory documents of entities including, but not limited to:

- Food and Drug Administration (FDA)
- Drug Enforcement Administration (DEA)
- Occupational Health and Safety Administration (OSHA)
- Department of Transportation (DOT)
- Environmental Protection Agency (EPA)
- Licensure and "Pedigree" regulations of the state Boards of Pharmacies or other state regulatory bodies of all 50 states
- Other state and local regulatory bodies, including state and local health and environmental regulators

HDMA's members recognize the need for this heavily regulated environment and view themselves as involved in a critical partnership with regulatory authorities to assure that the U.S. healthcare supply chain is secure, and that it reliably and efficiently delivers healthcare products.

In our view, some particular government initiatives or regulations have appeared to impose greater burdens than their benefits would seem to warrant. However, our members have

long supported regulations that help us maintain and retain the safety, potency and purity of the products we distribute throughout the healthcare supply chain.

Concurrent with our view that strong regulatory oversight, particularly for the safety and security of the products we provide, is necessary, it is HDMA's strongly held view that oversight by an outside party, OMB, is a critically important part of the regulatory development process. HDMA and its members believe that the overseeing, coordinating role that OMB plays is crucial for the following reasons:

- OMB has been able to take "a step back" and look at "the big picture" to help assure that the overall scheme of regulation, even when originating from different agencies and departments, is consistent and rational. From its vantage, OMB is able to help assure that the initiatives of one agency are not undermining the initiatives of another agency, and that two separate regulatory initiatives do not conflict.
- As an unbiased, outside observer, OMB is also able to help identify specifics in regulations under review that, while seemingly very clear to the agency staff who are closely familiar with the rule and their statutory authority to conduct a rulemaking, are not necessarily as clear to the business, industry, or product, that will be subject to the regulation. OMB can often point out areas in the regulations that would be ambiguous to the "lay" reader, can identify where compliance may be unnecessarily complex, and may facilitate appropriate clarifications before a regulation is finalized.
- As HDMA will discuss further below, OMB is able to serve as a "check" to assure that the agency has selected the least costly regulatory alternative commensurate with the safety or security goals that the agency is seeking to further.

HDMA SUPPORTS INCLUDING SPECIFIC ELEMENTS OF EO 12866 IN A REVISED EXECUTIVE ORDER, INCLUDING

The *Principles of Regulation* contained in Section 1(b)

Section 1(b), *The Principles of Regulation* contains clear, comprehensive directives for carrying out regulatory programs. These principles include: evaluating scientific and other data, assessing alternatives to direct regulation, seeking views of state and local officials, avoiding regulations that are incompatible with other regulations (including those of other agencies) and assessing costs and benefits.

These principles represent a "common sense" approach to rulemaking, and provide a timeless set of guidelines for proceeding along a path that is appropriate and attainable. Thus, HDMA recommends including Section 1(b) or a similar set of guidelines in the revisions to the Executive Order.

The requirement for Agencies to perform a cost-benefit analysis

In particular, HDMA and its members continue to support the requirements for preparation of cost-benefit analyses of proposed rulemakings. We have found on more occasions than is desirable that agencies consider the costs of new regulations or extensions of existing ones in a very cursory way. HDMA and its members emphasize that it is not, necessarily, the imposition of costs upon industry that is objectionable. Rather, that if those costs are to be imposed, decision makers should subject those requirements to a rigorous analysis to ensure that they have selected the regulatory requirement that is most likely to achieve the desired safety or security outcome in the most efficient and/or least costly manner commensurate with public health and safety.

This cost/benefit "check" that OMB provides is precisely why HDMA and its members are eager to see OMB oversight continue. Continuing OMB review of these regulations ensures that someone other than the agency who developed them, who may be invested in its continuance, objectively evaluates its cost and its effectiveness on an ongoing basis.

HDMA RECOMMENDS THAT OMB REEXAMINE, UPDATE AND REFINE THE DEFINITION OF "SIGNIFICANT REGULATORY ACTION"

As part of its recommendations to the President, HDMA suggests that OMB reexamine and refine the definition of "significant regulatory action." Currently, it is our understanding that under Executive Order 12866 and OMB Circular A-4, a regulatory action that would entail incremental annual costs of greater than $100 million triggers a cost-benefit analysis. Additional general criteria for determining whether the rulemaking is a "significant regulatory action" are also included in EO 12866. HDMA does not object to continuing the $100 million trigger. However, that level appears to be most appropriate for heavy industry which must make large capital expenditures to implement a regulation (e.g., re-engineering of large scale electric power generators or petroleum refineries).

In today's service industries and economies, large capital expenditures may not provide a full measure of a proposed regulatory action's impact. There are some industries that may feel a significant and even devastating impact far below that $100 million trigger. The Executive Order's other definitions of "significant regulatory action" are also valid, but given their indistinct nature, are not likely to result in preparation of a cost-benefit analysis as we believe would be desirable.

HDMA, therefore, encourages examination and inclusion of other potential measures of impacts to determine what constitutes a "significant regulatory action." These measures may have equal or greater significance than capital expenditures and/or costs of compliance necessary to undertake the proposed regulatory change. Some of the potential impacts/measures we

believe should be factored into a revised definition of "significant regulatory action" are included below.

- Imbalances created by a potential regulation may occur because of substantial differences in the business models within that single industry. Therefore, costs resulting from compliance with a new or extended regulation may have a far greater impact on some members of the same industry than on others and should be identified and evaluated during the development of the regulation.
- Reductions in the availability of a product or service, including the geographical availability of a product or service (such as rural vs. urban areas) may occur because the regulation may create greater costs and/or barriers to providing that product or service to some customers than to others.
- The regulation may inadvertently change and/or reduce the ability of existing industry members to compete on a "level playing field" and could cause distortions in the marketplace as a result (such as companies determining that they have no alternative but to exit the market). A regulation that could significantly alter the competitive landscape, even if costs are minimal, should be scrutinized closely.
- The regulation may inadvertently result in significant staffing changes or reductions. For example, if the affected business or industry must reposition existing staff away from business development efforts in order to effectively comply with new requirements, there may not be a direct "cost" to comply, but nevertheless, there may be a lost opportunity cost. In the extreme, if a business must reduce staff in order to meet the cost of compliance, the total impact of the regulation may not reach the $100 million level, but the impact may be devastating for employees and their families. A measure that evaluates employee/staffing changes may be appropriate.
- As noted above, costs associated with a new or revised regulation may not reach the $100 million level, but, if the regulation pertains to a smaller business or industry, a much smaller total cost may have a far greater impact than a larger cost to a larger industry. Alternative financial measures, such as a percentage of gross or net revenue should be considered.

HDMA also posits that when amending the Executive Order's definition of "significant regulatory action," it may also be appropriate to consider issues that are very specific to healthcare, such as whether the costs that are being imposed directly impact a life-saving product or service. Patients who receive a devastating diagnosis should have at least some reassurance that the cost of their treatment and/or medications was not increased by a regulatory requirement that could have been eased or eliminated. In such instances, greater scrutiny may be warranted with higher standards in place to assure that the agency action will achieve its optimum effectiveness, even if the cost is well below the $100 million level, and other current "significant regulatory action" criteria are not met.

In essence, HDMA believes that a "one size fits all" approach may not be as relevant in today's business environment as it was when EO 12866 was first issued. There is a wide

variability in size, structure, and types of business models, even within one industry. Thus, we believe it would be appropriate to consider this variability when updating the Executive Order and the regulatory review processes.

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In closing, HDMA is mindful of the cautionary notes of OMB Circular A-4 that it is not always possible to express in monetary units all of the important benefits and costs of a proposed regulatory action and that economic efficiency is not the only or even the overriding public policy objective. However, cost-benefit analysis is a very useful tool. Even where the most economically efficient regulatory route is not pursued due to other public policy, health and safety concerns, the utility of cost-benefit analysis lies in how it can inform the policymaking. Costs should be known, even where it is determined that they should be borne.

HDMA thanks OMB for this opportunity to comment upon so important an issue to regulated industry. If you have any questions or if HDMA can provide further information, please do not hesitate to contact me at

Sincerely,

Anita T. Ducca

Anita T. Ducca
Senior Director, Regulatory Affairs