PUBLIC
HEALTH
POLICY
ADVISORY
BOARD

May 21,2002

2175 K Street, N.W

Washington, DC 20037

(202) 775-11 10
(202)-775-1767 (fax)

E-mail:phpab@phpab.org

Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB
Room 10235
725 17th Street, NW
Washington, **DC 20503**

Sent electronically as a ***pdf*** file to jmorrall@omb.eop.gov

Dear Mr. Morrall:

We would like to thank Dr. John D. Graham and OIRA for the opportunity to comment on **OMB's** March **28,2002** ***Draft Report to Congress on the Costs and Benefits of Regulations.***

By way of introduction, the Public Health Policy Advisory Board is an independent, not for profit public health advocacy group founded and chaired by Louis W. Sullivan, MD, former Secretary of the US Department of Health and Human Services. Its goal is effective public health policy through a process of sound, science-based, policymaking.

The Board comprises broadly-based, multidisciplinary public health experts who cover emerging and current public health policies, science and data, improved processes for science-based policy **making, and public health policies and resource allocations.**

As former senior government officials, we understand the importance and difficulty **of** achieving government-wide direction, oversight, and coordination of regulatory policy to achieve public health objectives. We recognize that focusing public health resources where they have the greatest impact requires constructive thinking about risk management goals and choices.

We appreciate OIRA's vision of refreshing new standards in openness, transparency, analytic vigor, and promptness for oversight and review of government regulations.

Our focus for considering the Draft Report is the way it impacts those government activities directed toward health and public health. We view OIRA's efforts as a step by the Executive Office of the President toward achieving greater leadership and coordination for improving public health.

As we wrote in our February **14, 2001** letter to newly elected President Bush, we have had serious concern about the lack of public health leadership in the **US** government. The horrific events of September **11** and anthrax bioterrorism reinforced our view that effective public health leadership is an urgent need, with all due respect to the noteworthy responses of federal agencies after September 11.

Our February **14, 2001** letter pointed out that no single agency is charged with the responsibility for leadership or coordination of the federal government's diverse public health programs. The result is weakness and confusion in priority-setting and rational allocation of limited public health resources. We called for a serious reexamination of current national priorities and investments for children's health, particularly the major causes of mortality in children. Similarly, national priorities regarding health for all Americans should be brought into better alignment with the major causes of disease and injury.

Leadership and coordination are needed to address the problems identified in Justice Stephen Breyer's book ***Breaking*** the ***Vicious Cycle:*** Toward ***Effective Regulation,*** which the Draft Report cited. These include tunnel vision (the single-minded pursuit of a single goal carried too far, to the point where it brings about more harm than good), random aaenda selection (problems with the creation of regulatory agendas and with the establishment of rational priorities among the items that are included in those agendas), and, inconsistency (discrepancies in approaches to regulation within and among agencies and programs).

No other executive branch entity is as well positioned as OIRA to deal with tunnel vision, random agency selection, and inconsistency. From the Executive Office of

the President, OIRA is in a position to lead, coordinate and improve government-wide approaches to regulation, and assure consistency within and across the various public health agencies. Moreover, OIRA is in the pivotal position to consider costs and benefits not only of a single agency regulation, but also the costs and benefits in the larger context of overall efforts regulatory efforts by all public health agencies.

The development of government-wide priorities for regulatory efforts is essential to effective government resource allocation and management of regulatory burden. OIRA's experimental "prompt letter", a first effort in this direction, needs a more far-reaching focus to avoid itself becoming a piecemeal example of tunnel vision. OIRA's vision should be based on a broad OIRA perspective on trade-offs. Accordingly, OIRA should redirect the prompt letter to a broad initiative to lead and coordinate priority setting for overall agency public health efforts.

An ongoing challenge for the administration is to achieve an appropriate level of confidence in the benefit estimates used in regulations, singularly and collectively. Scientific information forms the basis for benefit estimates. In order to be able to provide leadership in priority setting, OIRA's oversight and review should extend to the science of how benefits are estimated. This will require sophisticated oversight and assessment by OIRA of the underlying science, data, methodology and assumptions used for estimates for regulations. As the National Academy of Sciences noted in its **1996** report ***Understanding* Risk, "**It is not sufficient to get the science right; an informed risk management decision also requires getting the right science, that is, directing the scientific effort to the issues most pertinent to the decision."

The Public Health Policy Advisory Board is a strong advocate of getting the right science and reducing random agenda selection. In order to help focus overall efforts to promote health and prevent disease, we have addressed populations at risk. We convened a major meeting on children's health in **1998** and issued a report in **1999** empirically demonstrating that the most likely and most serious risks to children were unintentional injuries, homicide, and suicide (from risk factors such as motor vehicles, alcohol, firearms) and that such risks were receiving disproportionately less attention than other less likely and less serious risks. In **2001** we updated this report on children's mortality and again called for addressing these serious risks to children as a priority. We recommend that OIRA

help lead and coordinate efforts to prioritize the reduction of risks to children, starting with the greatest causes of mortality and morbidity, as part of its responsibilities for implementing Executive Order **13045.**

The Draft Report identifies steps OIRA is taking to augment its internal science capabilities. The addition of a few staff with scientific expertise and establishment of an advisory committee will provide a modest increase to existing OIRA resources. OIRA's challenge is how best to deploy its resources to effectively assess agency submissions based on agency science and to develop uniform policies to strengthen OIRA's ability to assess the strength of the science used in cost benefit estimates. In the Draft Report OIRA identifies several other useful ways to strengthen the quality of science developed by the agencies including the new OIRA proposed standards for basic information and peer review. In order to ensure that the full range of credible scientific information is considered by OIRA and to address agency inconsistency, we recommend that OIRA provide ample opportunity for all agencies involved with public health to have their agency experts comprehensively comment on proposed regulations, regulatory alternatives, and costs and benefits as early as possible in the regulation development process.

Progress in public health for health promotion and disease prevention, from all sources including the prevention and detection of acts of terrorism, depends on further scientific discovery and technological innovation and its diffusion and commercialization. Probably, there is no greater potential regulatory area for the Executive Office of the President to address than new approaches to public health based on emerging science and innovative technology. The Draft Report recognizes that OIRA can offer valuable leadership and coordination for dealing with complex science-based regulatory issues by becoming involved at the planning stages rather than coming in only at the end when it is more difficult to make modifications. Accordingly, the final version of the Draft Report should describe overall policies designed to promote and avoid discouraging innovative science and technology that have the potential to further add to the quality of life. The policies should address the fact that scientific knowledge and innovation, which can save lives and reduce suffering, often develop at a very rapid rate, yet changes to regulations affecting the commercialization of such innovation typically occur at a more glacial pace.

The Draft Report describes OIRA's interest in the review of existing rules that should be rescinded or changed to increase net benefits by either reducing costs or increasing benefits. In sectors marked by rapid scientific discovery and innovation, ideally such rules should receive routine review. For example, in the 1980s when biotechnology appeared poised for commercialization, and the involved regulatory agencies were beginning to develop various regulatory approaches, OIRA participated in achieving an effective overall coordinated framework for the regulation of biotechnology by all the involved agencies. After some 15 years of experience much more is known today from a scientific perspective regarding the costs and benefits. It would appear timely for OIRA to review the overall costs and benefits of the rules that form the coordinated framework.

The Draft report describes a public nomination process for nomination of existing rules to be targeted for agency reviews. This should not preclude OIRA self-initiating efforts to oversee and deal with problems of tunnel vision, random agency selection and inconsistency, whether in an existing rule or in an agency's planning process, particularly when agency messages appear to conflict. For example, while there are a myriad of substances that might potentially impact public health, substantial resources have focused on dioxin. The messages are contradictory: on the one hand, dioxin presents a significant cancer risk and the primary source of dioxin exposure is through food, yet, on the other hand, the food supply is safe.

We strongly support the initiatives in the Draft Report for greater transparency in the use and dissemination of scientific information by the agencies. We would urge that these efforts continue to expand as a means to achieve consistently high quality science across public health regulatory agencies.

The Draft Report notes OIRA's role as an "overseer of analysis and information quality" including that used in statistical reports and regulatory impact analyses. We believe that this area could benefit from greater OIRA oversight. The Public Health Policy Advisory Board recently released a report on asthma. In noting the well-recognized epidemic increase in asthma morbidity and mortality, the report highlighted weaknesses with the government's data, in part generated by a change in the case definition of asthma and inconsistent approaches to age and racial groupings. The report recommended (1) the standardization of

methodology and data describing asthma in order to generate effective public health policy for asthma, and (2) a careful examination of the evidence underlying the epidemic increase in disease prevalence and mortality to gain an understanding of the cause of the epidemic. We support OIRA establishing and enforcing policies to maintain the highest quality for government information.

In closing, we have a several suggestions for achieving health promotion and disease prevention. In developing regulatory approaches for achievement of public health objectives, we encourage consideration of the possible costs and benefits from greater individual and family responsibility for health promotion, disease prevention and treatment. Similarly, we believe that the private profit and nonprofit sectors often have much that they can contribute to the achievement of public health objectives. Accordingly, regulatory approaches should consider the costs and benefits of providing flexibility to the regulated communities to encourage their development of innovative solutions to achieve public health objectives.

Likewise, while developing and reviewing regulatory approaches, we want to reiterate the important role of State and local governments (including communities), noted in the Draft Report. Public health is substantially addressed through these levels of government, close to the people the policies seek to help. We urge that regulatory approaches consider the costs and benefits of offering these levels of government appropriate discretion to fashion approaches most suited to their particular situations and requirements, as noted in the OECD reference check list for regulatory decisionmaking.

Thanking you for the opportunity to comment, I am,

Sincerely,

John J. Cohrssen

John J. Cohrssen
Executive Director