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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 10 1997

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM TO AGENCY CHILDREN'S EXECUTIVE ORDER CONTACTS

From: Gary S. Guzy 
Counselor to the Administrator

Subject: Proposed Revision to Draft Executive Order

As you know from our several discussions, EPA believes that one of the principles underlying the Executive Order should be our efforts to share with the public how much we do and do not know about the effects of regulatory actions upon children. The current draft (2.5.p.m.1) generalizes this objective through the annual report requirement in section 3-304. While useful, we do not believe that this goes far enough in addressing the draft Order's basic objective of either protecting children, affirmatively explaining why an agency may be making a different choice, or indicating that information is lacking to allow for a fully informed decision on child-specific concerns.

At the same time, we are very mindful of the concern expressed by a number of agencies that the Order not require agencies to set forth a "Kick Me" sign with findings that could have adverse litigation consequences.

We therefore propose including the following language, added as subsection (d) of 5-501:

"A description of the data or information, if any, which was employed to assess child-specific risks or hazards."

It is our view that this language would move towards providing more transparency in the context of particular rulemakings, but that it would remove any adverse judgments from such statements and the likelihood of any statements being used successfully against an agency in litigation. It is intended only to require neutral explanations of the information used to reach the judgments contained in a regulatory action.

Please contact me at (202) 260-7960, or Bob Dreher at (202) 260-8040 if you would like to discuss this approach further or if you have any particular concerns about it. Thank you for your continuing prompt attention to this matter.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

COPY

National Institutes of Health
National Institute of Child Health
and Human Development
Building 31, Room 2A03
31 Center Dr. MSC - 2425
Bethesda, Maryland 20892 - 2425
Phone: (301)496 - 3454
FAX: (301)402 - 1104

DATE: February 4, 1997

TO: Leslie L. Clunc
Associate General Counsel, Office of the General Counsel, OS

FROM: Director, National Institute of Child Health and Human Development, NIH

SUBJECT: Proposed Executive Order Entitled "Protection of Children in Federal Environmental, Health, and Safety Actions"

COMMENTS ON DOCUMENT #154954

The NIH has serious concerns about this draft Executive Order. The topics it is intended to encompass are inconsistent, unclear, and confusing throughout the document. Commas make a big difference here. It is one thing to address protecting children in environmental health and safety actions. It is far broader and more complex to do so for environmental, health and safety actions, where health and safety must be considered separately and not just in relation to the modifier "environmental." If the intent is to have this order affect just environmental health and safety concerns, as much of the language implies, the wording needs extensive revision to make this clear. If not, the effects are so broad that this issue needs extensive discussion--it is inappropriate to be asked to agree to something this sweeping out of the blue in one day. The aim is difficult to take issue with, but the mechanism and scope need discussion.

Duane Alexander, M.D.

TO: Joel Johnson
FROM: Susan DeLaurentis
DATE: December 5, 1996
RE: Pediatric Data for Pharmaceuticals

Thank you for your willingness to pass along our proposal to the appropriate White House staff for such matters. As you have requested, I will briefly describe here the "best case scenario" from our view. We have been discussing this issue (i.e., the need for pediatric data) with David Kessler, Bill Schultz (his deputy), and their lawyers over the past year, and I think you will find them supportive as well. Everyone has put a lot of time into this and it has been productive.

The following scenario presents the President with the most visibility on what we believe will be a very popular, "Christmas-present-to-all-children" initiative. If this seems right to the White House, we can -- and must -- begin work immediately. (It would be particularly helpful if there were a White House staff contact for us. With most of our issues we would go directly to the AIDS staff, but this is obviously broader than AIDS alone.)

We propose that some time during the week of December 16, the President issue an Executive Order, directing the FDA to take immediate regulatory action to ensure that all drugs be proven safe and effective for use by children prior to their approval by the FDA. We propose that the President sign the Order in the Oval Office, with children, parents, and pediatricians present. We would ask that the President dedicate this action to Elizabeth Glaser and her work to improve child health, and that the Pediatric AIDS Foundation be included in the event.

A proposed action plan detailing the steps that need to be taken, including what should be included in the President's Executive Order and accompanying statement, is attached to this memo. We would be happy to help in effectuating this plan in any way possible -- from drafting the Executive Order, to generating support in the media, to making physicians, parents, and advocates available for comment. Just let us know what we can do.

We are very excited about this proposal, and appreciate your attempt to steer us toward the appropriate decision makers.


Thanks again for everything.

U.S. Department of Labor

Assistant Secretary for Policy
Washington, D.C. 20210



January 31, 1997

MEMORANDUM FOR: BRADLEY CAMPBELL
FROM: SETH HARRIS 
SUBJECT: Preliminary Comments on the Children's Environmental
Health Executive Order

You asked that we send you preliminary comments on the draft executive order (E.O.) for inclusion in the version being prepared for Monday. We will have additional comments next week.

As indicated during the conference calls, DOL's preference is to limit the E.O. to children under the age of 14. This could be accomplished in the definitions section and by including a statement in the opening section along the lines of EPA's comments this morning (e.g., the science indicates problems manifest in younger children; therefore, the focus of the E.O. is on children under 14). We would be willing to explore other options for excluding teenagers 14 and older.

An alternative (but less acceptable) approach would be to insert the following language into the opening section:

While some health or safety agencies have statutory missions predominantly directed toward certain age groups, such as the working-age population or the elderly, other agencies have more general mandates to protect public health or the environment for the benefit of all Americans. The intent of this Executive Order is to assure that the latter agencies adequately consider health and safety hazards to children when developing regulations and programs.

If the final decision is to include older teenagers, we recommend the following language changes:

- Section 3-302. The Department of Labor should be included in the IWG. NIOSH should also be included because it does the bulk of the research on occupational safety and health.

- 2 -

- Section 3-303(c). Cut sentence requiring pamphlet. Allow IWG to determine best outreach approach.

- Section 6-601. Suggest "For each significant regulatory action initiated after the effective date of this E.O. that addresses the environment, health or safety, each agency shall provide the following information, to the extent practicable, ..." We need some language to assure that these requirements do not (1) interfere with current rulemakings, and (2) impose huge analytical burdens on the agencies. OSHA risk assessments and regulatory analyses already consume considerable resources.

FDA COMMENTS ON
DRAFT EXECUTIVE ORDER TO PROTECT CHILDREN
FROM ENVIRONMENTAL HEALTH THREATS

- While parts of the draft executive order (such as the second bullet) appear to address a wide range of health threats to children, other parts (such as the title and first bullet) appear to be limited to environmental health threats. FDA recommends that the scope of the executive order be broadened beyond just environmental health threats. Limiting an executive order to environmental health threats could imply that the most significant health threats faced by children are environmental ones. In FDA's view, while environmental threats are important, they are not the only significant health threats faced by children.
- While FDA recognizes the benefit of focusing specific attention on health threats to children, FDA is concerned about layering additional requirements on the regulatory process in circumstances where they will not add "value" to the process. Thus, FDA recommends that any new analysis regarding effects on children's health be targeted at regulations that (1) have potential disparate health impacts upon children and (2) are significant regulatory actions as defined in Exec. Order 12866.

The first limitation (that an analysis of effects on children be limited to regulations with a potential disparate impact on children) will insure that new regulatory reviews are not required unless there is a specific reason to be concerned about children. The second limitation (that an analysis of effects on children be limited to significant regulatory actions) will target the new analysis to the regulations which have the greatest effects and which are already required to be subject to a formal cost-benefit analysis. If the executive order is targeted in this way, it will formalize what FDA should be -- and is -- already doing.

- The draft executive order requires that certain regulations be "adequately protective" of children's health. FDA suggests that this standard be made less vague and more affirmative by requiring that the regulations "protect" children's health. In addition, whichever standard is used, it may be necessary to clarify that the requirement to protect children's health applies "to the extent permitted by law." Without such a qualification, the executive order could be construed as an attempt to override existing statutory authorities.
- The draft executive order also requires an "affirmative finding" that certain regulations are adequately protective of children's health. A better approach might be to follow the Food Quality Protection Act and require "a specific determination regarding the safety ... for infants and children" (sec. 408(b)(2)(C)(ii)(II)). The specific determination language has the advantage of not requiring an affirmative finding where this would be impossible due to lack of complete information or a conflicting statutory mandate.
- FDA does not object to restricting the pamphlet for families (which is addressed in the third bullet) to just environmental health threats. However, FDA does have questions about implementation, including whether the pamphlet is a one-time project or an annual one, whether a significant commitment of resources will be required, and who will take the lead in preparing the pamphlet.



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

Office of the Executive Director

MEMORANDUM

DATE: January 31, 1997

TO : Brad Campbell
Associate Director
Council on Environmental Quality

Mac Reed
Office of the General Counsel
Executive Office of the President
Office of Management and Budget

FROM : Pamela Gilbert PG
Executive Director

SUBJECT: CPSC Staff Comments on 1/30/97 Draft of the Children's Health and Safety Executive Order¹

We want to reiterate that, as an agency with no greater priority than protecting the health and safety of children, we strongly support the stated intent of the draft Executive Order -- to establish a "national policy to protect the health of American children from environmental, health and safety hazards." We had a number of serious concerns about the previous draft of this Executive Order, and we are pleased to see many of the changes that have been made to address those concerns.

This memo outlines our most serious remaining concerns with the contents of the current draft Order. We also anticipate that we may have more comments, questions, and recommendations once we have reviewed the comments of other participating agencies. Finally, we are still reviewing the Preamble to the draft Order, and may have further comments after that review is completed.

Section 1-102: This section is overly prescriptive and could arguably require agencies to spend unlimited resources to address a particular hazard, unless prohibited by statute.

Proposal: Section 1-102 should be modified to read, "The head of each Federal agency shall ensure that the potential impacts upon children of environmental,

¹This memorandum does not necessarily reflect the views of the Commissioners.

health, or safety hazards arising from or related to the activities of that agency are considered and addressed, as appropriate, by that agency."

Section 3. Children's Health IWG

We agree that there needs to be coordination among federal agencies on children's health and safety issues, particularly in the area of research. However, as originally drafted, the Executive Order would have established a new Children's Environmental Health Council with a broad mandate that went well beyond simple coordination among agencies. CPSC staff commented that the creation of a new, cumbersome bureaucratic entity was counter to the Administration's reinvention efforts, and that its broad responsibilities could impose inappropriate burdens and mandates on member agencies. While we are pleased that the original proposal has been considerably scaled back, we still have a number of concerns about the proposed Interagency Working Group (IWG).

Sections 3-301 and 3-302. We agree with many of the comments that have been made by representatives of the Office of Information and Regulatory Affairs (OIRA) about creating a new bureaucracy to coordinate efforts among agencies. We are eager to review OIRA's written comments and recommendations to revise this proposal.

Section 3-303. We have a number of questions and concerns about the list of elements that make up the coordinated Federal strategy:

- (a) What is meant by statements of "guiding principles" and "general policy?" How would those principles and policies differ from what has already been stated in the Executive Order? We would be strongly opposed if those principles and policies included specific directions regarding scientific or technical assessments done by individual agencies.

Isn't it redundant to require a statement of "targeted annual priorities" in this subsection when subsection (d) lists the same requirement? How would these priorities differ from those mentioned in (d)?
- (b) As an agency with a broad mandate and a very limited budget -- and no separate research budget -- we would oppose any requirement for the CPSC to contribute in any manner to a "cross-cutting budget" for conducting research.
- (c) We support a coordinated effort to reach out to, and educate the public about, health and safety risks to infants and children. However, we believe it is inappropriate to dictate the form of that outreach by requiring the publication of a pamphlet that includes specific information.
- (d) There is no reason to require the identification of a specific number (ten) of

high-priority initiatives for the Federal government to undertake.

Proposal: Subsections 3-303 (a), (b), (c), and (d) should be modified as follows:

- (a) Delete this subsection entirely.
- (b) Delete the requirement to prepare a cross-cutting budget.
- (c) Delete the second sentence of this subsection.
- (d) Delete the word "ten."

Scope: CPSC already focuses its priorities and efforts on protecting children from injury and death. We endorse an Executive Order to help advance children's health and safety issues government-wide, and would recommend that the CPSC adhere to its terms. However, it would be inappropriate, for example, to alter an independent agency's statutory rule making requirements through an Executive Order.² Indeed, the administration implicitly recognized this principle in E.O. 12866, which exempts independent agencies from its provisions that directly affect an agency's regulatory authority (see E.O. 12866, sec. 6), and requires those agencies only to prepare a "regulatory plan" and "regulatory agenda." (E.O. 12866, sec. 4(b) and (c).) Similarly, we believe that CPSC should be part of any Interagency Working Group that is created and submit research proposals for consideration, but that CPSC should otherwise be exempt from the draft Executive Order's requirements.

Proposal: The following language, quoted directly from E.O. 12866, should replace the definition of "federal agency" in section 2-201:

"Agency," unless otherwise indicated, means any authority of the United States that is an 'agency' under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502[(5)]."³

²As the Supreme Court has held, an independent agency

"cannot in any proper sense be characterized as an arm or an eye of the executive. Its duties are performed without executive leave and, in the contemplation of [its enabling] statute, must be free from executive control." Humphrey's v. United States, 55 S.Ct. 869, 874 (1935).

³ Since the issuance of E.O. 12866, 44 U.S.C. 3502(10) has been renumbered as 44 U.S.C. 3502(5).

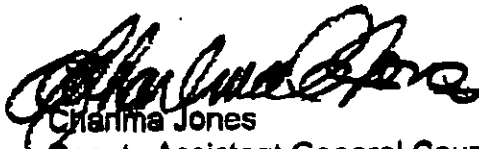
January 31, 1997

To: Mac Reed
OMB

From: Department of Veterans Affairs

Subject: Proposed Executive Order Entitled "Protection of Children in Federal Environmental, Health, and Safety Actions"

As relayed on my voice mail to you on this date, the Department of Veterans Affairs has concerns about the proposed Executive Order (EO) because the vagueness and ambiguity of the requirements makes it difficult to determine applicability. For example, the term "potential impacts" needs to be clarified in such a way to better define and/or limit when a federal agency must consider the effect of what it does on the health and safety of children. The definition of "significant regulatory action" should be clarified to exclude regulatory actions which are unlikely to affect the health and safety of children. The annual reporting requirement in Section 5-501 should be discretionary so that a report will not be required if an agency determines that there is nothing to report. It is also unclear what impact the proposed EO will have on an agency's budget for research or the degree to which the EO will impact an agency's contractual relations.




Charina Jones
Deputy Assistant General Counsel
273-8615

THE WHITE HOUSE
WASHINGTON

June 21, 1996

MEMORANDUM FOR T.J. GLAUTHIER

FROM: Carol Rasco 
SUBJECT: Family Right to Know Initiative

The Family Right to Know Initiative is a very positive concept that has the potential to fill an important void in the current protection of children's health from environmental risks. When parents and families know about the unique risks to children they can use that information to make wise choices. Responsible decisions by parents can have an aggregate benefit today and in the future.

In framing this concept we have agreed to a commitment to work with parents, scientists, the business community, and others to achieve the goals of getting better information to families. As we work with the stakeholders we can build on the concept of a family's right to know, and decide whether legislation is or is not needed to achieve our goals. As the Administration moves forward we should continue to emphasize our belief that we can achieve our goals in a common sense, cost effective way. That emphasis is needed to respond to concerns that we will put into place unnecessarily expensive approaches.

I plan to continue to be involved in this initiative; please contact Diane Regas of my staff with new information as it arises.

February 10, 1997

To: Bradley Campbell

From: Fred Siskind

Subject: Comments on the revised discussion draft of the Children's Environmental E.O.

While we believe the revised discussion draft of the Children's Environmental E.O. is much improved, as I noted in the voice mail I left for you on Friday, it still presents problems for DOL programs. We have developed several options that we believe would eliminate the burden for DOL without affecting the basic thrust of the E.O. As you know, our particular concern is that OSHA and MSHA focus on workplace hazards regardless of who is exposed. They do not address risk to particular demographic groups, but to all workers.

The following options are in order of our preference, with one of the first three strongly preferred to the fourth:

Option 1. Add to definitions: "Environmental, health, or safety risks include only those risks or hazards to which members of the general public regularly may be exposed."

Option 2. Add to definitions: "Federal agency includes those agencies listed as members of the IWG in Section 3-302 and such agencies as may be designated at a later date." In addition, the phrase "but are not limited to," should be stricken from Section 3-302.

Option 3. Add to definitions: Disproportionate or disproportionately affect does not include any safety or health hazard or risk that occurs in workplaces in which the regular exposure of significant numbers of children to the hazard or risk cannot reasonably be anticipated.


Option 4. Add to definitions: Disproportionate or disproportionately affect does not include any safety or health hazard or risk that occurs in workplaces in which the regular exposure of children to the hazard or risk cannot reasonably be anticipated.

If you have any questions, please call Seth Harris (219-6181) or me (219-6197).

THE WHITE HOUSE
WASHINGTON

January 27, 1997

MEMORANDUM TO Bruce Reed
 Elena Kagan

FROM: Diane Regas 

SUBJECT: Environmental Issues for State of the Union

There are two leading ideas for an environmental message in the State of the Union Address. This memo gives you a short background and status on each.

Protecting Kids

Background

In August the President directed federal departments to identify ways to provide better information to families about products that pose a special risk to children. Since that time, EPA has been working on a proposal to fulfill this direction. The proposal on the table has two components: first is an Executive Order that would direct federal departments to consider all information about risks to kids when developing environmental health standards, second is principles for toxics labeling legislation.

The Executive Order, the "Children's Environmental Health Executive Order" would require departments, when taking regulatory action, to make a finding either that the action protects children or that there is insufficient information to make such a determination. In addition, the draft creates a "Children's Environmental Health Council" to oversee the implementation of the Executive Order, to coordinate federal research, and, among other duties, to consult with OIRA on regulatory actions that may affect children's environmental health.

The primary conceptual questions about the Executive Order are: which federal actions should be covered; how should federal departments deal with limited information; and whether the Executive Order is consistent with the Administration's position on regulatory reform legislation. The draft text has been in circulation only a few days, and I expect that new issues will arise based on the text. (Our next interagency meeting is Tuesday, January 28.)

The second part of the proposal, principles for labeling legislation, would express the Administration's support for a requirement that manufacturers label products with information about special risks to children. This proposal is modeled on "Proposition 65" a ten year old law in California. The key to the proposal is that it does not add to government regulation of product content, instead it requires manufacturers to test products and label them

appropriately. The government's role is limited to identifying which substances are of concern, and perhaps identifying level below which labeling will not be required. Proponents of this approach argue that labeling will provide families with the tools they need to make choices among products and create a strong incentive for manufacturers to reformulate potentially unsafe products. The proposal would exempt food and drugs.

Federal agencies and White House staff have raised concerns about legislation in this arena. There is little solid data regarding the costs and benefits of a national proposal, and the California model has not been rigorously studied. (We lack data on the costs and benefits of the California law partly because companies have been very reluctant to release information about their costs.) In addition, there are difficult trade and small business implications that need to be hammered out.

Status

The Executive Order is in draft and could probably be finalized quickly if EPA generates support within the White House for that position. The process of coming to closure quickly could, however, cause us to miss some more subtle issues, and will likely lead us to draft an Order that is narrowly tailored to environmental health, rather than considering an approach that applies to all health-based regulations.

EPA has drafted about a dozen principles to support labeling legislation. While these too could be finalized for the State of the Union, the lack of detailed understanding of the policy and political implications counsel continuing the staff discussions. Both OMB and NEC have serious concerns about the need for legislation, and how to structure it most efficiently. (Recall that EPA proposed this concept at an NEC meeting in June and the proposal was tabled.)

Recommendation

The President should commit to issuing an Executive Order to ensure that federal decisions use the best information we can get to protect children, or more narrowly, children's environmental health. The interagency process to finalize the Executive Order could then be completed in coming weeks.

The discussion of legislative principles should be brought to a deputies' or principals' meeting to allow for a full airing of the issues.

American Heritage Rivers

Background

A new proposal to create a federal designation "American Heritage River" is being discussed in a process convened by CEQ. The President would announce a commitment to this idea and work some of the details, including an Executive Order, later. Currently CEQ staff is proposing that identification be based primarily on the cultural value of rivers. The implication of designation is still under discussion, but would include a call for partnerships with the private sector, federal support for local initiatives and federal steps to protect designated waters. Initially departments have raised some concerns: a designation process

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will create false expectations that we can solve problems in many places; choosing waters for cultural significance conflicts with targeting environmental money to solve problems; as described, the new designation does not clearly add to current work; and we have not thought through potential political opposition.

The biggest challenge we face in making this idea work is to make designation as an American Heritage River meaningful. I am continuing to work with CEQ as they identify ways to accomplish this goal, but I remain concerned that we may not have good solutions by next week. I have attached the current iteration of this idea.

Status

CEQ staff are committed to adding enough detail to a proposal so that a decision can be made about whether to go forward next week. They envision that further detail would be developed in coming weeks.

Recommendation

There are thousands of people across the country who are working to restore enjoyment of their local waterways, and who would welcome new tools to achieve their ends. They need incentives to create jobs and revitalize rundown urban waterfronts; small grants to catalyze their work; better processes for participating in federal decisions; more information about environmental threats in their local area; and a federal commitment to work in ways that are consistent with local needs. We can do this, and we should focus the effort where people really need it--urban waterways. The current proposal, if it remains focussed on historically or culturally significant waters, is unlikely to bring these tools to communities.

White House staff should be tasked with coming up with an urban waterways initiative that contributes jobs and environmental benefits. Such an initiative could be announced in a few months.