TESTIMONY

BEFORE

THE DOMESTIC POLICY SUBCOMMITTEE

OF THE

OVERSIGHT AND GOVERNMENT REFORM COMMITTEE

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Good Afternoon Mr. Chairman and Members of the Subcommittee. It is a pleasure to appear before the Domestic Policy Subcommittee on the important and timely issue of the classification of dental mercury amalgam and the Food and Drug Administration's obligations under the National Environmental Policy Act (NEPA).

Allow me a brief moment to provide you my background. I am the Senior Partner with the Clark Group, a Washington-based environmental and energy consulting firm. I left public service in 2001 as the Principal Deputy Assistant Secretary of the Army for Installations and Environment. From 1992 until 1999, I served in the Council on Environmental Quality in the Executive Office of the President. I have been teaching NEPA implementation at Duke University since 1989 and I am the editor of a book on the history of the passage of NEPA, the current principles and practice and the future of the statute and practice.

When Congress passed NEPA in 1969, they recognized the complexity of environmental issues and the role of the federal government in the perturbations and improvement in the human environment. Congress also recognized it was not only the direct effects agencies may have, but the many policies, regulatory actions, and the effect on markets. NEPA provides the nation with an environmental policy, a tool to reach that policy, and an agency within the Executive Office of the President to ensure that agencies understand the policy in Section 101 of the Act and to develop and oversee the development of procedures to comply with the law.

With the passage of NEPA, Congress established the Council on Environmental Quality (CEQ) and directed the federal agencies to work with governments at all levels to begin the arduous task of understanding the effects of manifold actions taken in the absence of full information. No statute has offered a more structured and disciplined approach to federal decision-making and no statute has offered the public as transparent a window into federal decision-making as NEPA. No statute has given the agencies more flexibility to establish the ways and means of meeting their mandate.

Since the passage of NEPA, Congress, CEQ and the courts have responded to the uncertainties of human experimentations on the natural landscape through statutes, regulation and court decisions. All have given great deference to the agencies, but they have all asked the agencies to take a "hard look" at proposed actions to try to ascertain the direct, indirect and cumulative effects of such actions. Over the course of time and with the help of NEPA and the agencies' hard look, we know more today about the effects of many federal actions, whether they be policies, projects, or programs. We also know more about how complex the environmental interactions are. We also understand that our collective environmental knowledge gap is wide.

Through the work of the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and other public and private science, we now know that Mercury is a highly toxic, persistent and bioaccumulative neurotoxin. We know that it is released into the air through burning of coal at power plants and burning of mercury-containing wastes. It is released into water either indirectly by deposition or directly to wastewater treatment plants or in sludge generated by the treatment plant. Typically, this sludge is composted or incinerated. Once mercury reaches a water body through rain or snow, bacteria convert it to a more toxic form, methylmercury, which accumulates in the tissues of plants, insects, fish, and animals.

A major source of mercury amalgam comes from the dental devices used by dentists. According to an EPA cradle-to-grave study on the use and release of mercury, the amalgam in wastewater from dental offices is the largest direct contributor of mercury to water in the United States at 7.4 tons/year.[1] As is often the case with environmental knowledge, the receptors often feel the impacts much sooner than the source understands the effects of the action. In this regard, wastewater treatment agencies were the first to detect and try to address mercury discharges by dentists. However, these waste water treatment agencies have limited jurisdiction, and their regulatory mechanisms vary. Some have adopted new bylaws specifically addressing the issue, while others relied on enforcing limits already in place, and still others negotiated special limits for dental offices. The resulting patchwork system means that dentists living in one county or city may be required to act differently than those in the adjoining jurisdiction.[2]

Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Oregon, and Vermont have all implemented some form of law requiring dental offices to use amalgam separators. Amalgam separators capture mercury amalgam from wastewater effluent for recycling or other disposal. In addition, several countries including, including Canada, Sweden, Norway, Germany and Austria have now taken or initiated steps to reduce or eliminate

[1] U.S. Environmental Protection Agency. 2002. *Use and Release of Mercury in the United States.*
[2] Savina, G. 2003. *Mercury in Waste Dental Amalgam: Why Is It Still a Problem?* Local Hazardous Waste Management Program in King County. Retrieved online from http://www.govlink.org/hazwaste/publications/WasteAmalgamProblems_03.pdf.

the use of amalgam as a dental restorative material. These steps were taken by governments to control what was perceived as a potential threat to the human environment. A number of organizations, such as FDA, and scientific experts have studied the potential impacts of dental amalgam as used on humans. However, there are limited scientific studies on the fate of dental amalgam in the environment, and the wide range of results in these studies stop short of a comprehensive "hard look" at the potential impacts.

In my opinion, it seems clear that at least one of the two following conditions exist: (1) there is a clear environmental effect of the manner in which mercury amalgam is being treated and disposed or (2) there are scientific uncertainties about the extent of environmental effects. Any statement that there is no environmental effect would be met with argument and likely scientific controversy, as we see today. In either situation, however, there is a responsibility of the Food and Drug Administration to understand these effects or the differing scientific views before making a decision. NEPA requires such understanding before FDA can make a decision on risk classification.

There are three ways the FDA could meet the requirements of NEPA and CEQ regulations and document the agency has taken a "hard look". One is through development and deployment of a categorical exclusion. In order to categorically exclude such an action as a rulemaking on classifying dental mercury amalgam, the FDA would have to reach one of two possible conclusions; either that mercury amalgam inherently has no significant individual or cumulative environmental effect or through the experience of numerous environmental assessments which consistently found no significant impact.

It seems clear that FDA cannot categorically state there is no significant impact of the rulemaking at hand. How do they know? They have not completed a comprehensive environmental assessment of which I am aware and the literature and experience would not bear out that there is inherently no significant effect. At a minimum, there is some scientific disagreement on this point and that alone would be enough to preclude a categorical exclusion. There are uncertainties associated with the use of dental amalgam, such as the amount discharged from dental offices; the fate of the mercury in amalgam; and the percentage of elemental mercury that is released from amalgam.[3] There are also others in state and local government taking precautions to assure safety and that should clearly indicate to FDA that the effects of the rule are not "inherently insignificant".

The second way FDA could categorically conclude there are no significant effects is by preparing one or more environmental assessments, each of which reaching a finding of no significant impact. In fact, in 1997 FDA responded to a question about whether secondary and tertiary manufacturing processes involving food additives that may result in uncontrolled end products should be categorically excluded. The agency responded appropriately, in my opinion, because they reviewed hundreds of environmental assessments that contained information regarding manufacturing sites and found no significant impact, and so they decided to categorically exclude the process from further analysis.

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[3] U.S. E.P.A. and Environment Canada. 2004. *Options for Dental Mercury Reduction Programs: Information for State/Provincial and Local Governments.* Retrieved online from http://www.epa.gov/region5/air/mercury/dentaloptions3.pdf.

To my knowledge, no comprehensive environmental assessments have been prepared on the issue of dental mercury amalgam. It seems to me that such an assessment could help clear up some of the potential impacts or the scientific uncertainty. Although FDA and the agencies have reviewed the potential risks of the use of dental amalgam in humans, it is not clear that they have taken a look at the risks associated with use of dental amalgam and its fate as it moves through the human and natural environment in water, air and soil. At the same time, there exists disagreement concerning the amount of mercury currently captured in dental offices and 'captured' mercury is not necessarily sequestered from the environment depending on the method of disposal. The mercury discharged by dental offices may fall within the purview of many agencies, each approaching the problem through its particular regulatory lens. Each agency can move the mercury to a different media and a different set of regulations without removing it from the environment. No one agency addresses the cumulative long term effects of mercury discharges, and there is no assurance that the mercury is ever effectively sequestered.[4]

FDA may be right that the environmental effects associated with the level of use of dental amalgam are not significant. However, I cannot see how they have come to the conclusion. They have not produced any environmental assessments or impact statements, and the literature and practice is rife with questions about the use and disposal. It is precisely the type of policy that the authors of NEPA thought should be subjected to the rigors of analysis. The rulemaking action clearly is a significant action anticipated by NEPA. CEQ regulations define a major federal action as "actions with effects that may be major and which are potentially subject to Federal control and responsibility." Actions also include the "circumstance where the responsible officials fail to act and that failure to act is reviewable by courts or administrative tribunals under the Administrative Procedure Act or other applicable law as agency action." Further quoting from the CEQ regulations defining a major federal action: "(a) Actions include new and continuing activities, including projects and programs entirely or partly financed, assisted, conducted, regulated, or approved by federal agencies; new or revised agency rules, regulations, plans, policies, or procedures; and legislative proposals (Secs. 1506.8, 1508.17).

Federal actions, according to the CEQ regulations include the "adoption of official policy, such as rules, regulations, and interpretations adopted pursuant to the Administrative Procedure Act, 5 U.S.C. 551 et. seq." Further quoting CEQ regulations, "Adoption of formal plans, such as official documents prepared or approved by federal agencies which guide or prescribe alternative uses of Federal resources, upon which future agency actions will be based," would be considered a major federal action.

Once the action is deemed to be a "major federal action", the FDA must determine the appropriate level of analysis, that is, whether to conduct an Environmental Assessment or an Environmental Impact Statement. This can be accomplished using a number of factors to determine the potential significant environmental effects of the action. The CEQ regulations define significance as "context and intensity" (§ 1508.27). For context, some of the factors to consider include the affected region, society (human, national), and locality. It also includes the short-term and long-term potential to effect the environment. Intensity refers to the severity of the potential impact, including degree of impact, degree of controversy, and the cumulative

[4] Savina, G. 2003. *Mercury in Waste Dental Amalgam: Why Is It Still a Problem?* Local Hazardous Waste Management Program in King County. Retrieved online from http://www.govlink.org/hazwaste/publications/WasteAmalgamProblems_03.pdf.

effects of the action. The way these factors are identified and evaluated under NEPA is through a scoping process.

Mr. Chairman, there are ways such an assessment could be done efficiently and effectively. FDA could prepare a Programmatic Environmental Assessment. If indeed the agency could answer the questions being posed by sewage plants, by cities and counties, and by health officials, perhaps many resources could be saved by these authorities; perhaps FDA could identify mitigation techniques that would render the impacts insignificant; perhaps a collaboration between FDA and other federal, state and tribal governments would emerge and programmatic approaches could be developed. A forward looking FDA in 1978 filed a programmatic EIS regarding use of fluorocarbons in products subject to FDA regulation. The EIS was used as a basis for prohibiting CFCs as a propellant in self pressurized containers if the use of the CFC was not deemed to be essential. This action seems all the more responsible in hindsight.

In conclusion, Mr. Chairman, there is much to commend in the FDA NEPA regulations. There is sound environmental policy, transparency, an admonition to prepare readable environmental analyses for the public, and solid streamlining efforts which we should all support. FDA has in the past used EISs for sound decision-making. However, on the question of whether there is sound footing to declare a categorical exclusion for rulemaking for classification of risks, I do not see the basis. I would recommend to FDA to prepare a Programmatic EA on the rule and allow the scientific community and the public to offer their advice and counsel before asking the decision-maker to decide in the absence of any environmental impact analysis.

Thank you and I would be pleased to answer any questions.