July 28, 2008

Dr. Andrew von Eschenbach
Commissioner
U.S. Food and Drug Administration
5600 Fischers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

I am writing regarding the U.S. Food and Drug Administration's (FDA) statutory duty under the National Environmental Policy Act of 1969 (NEPA) to prepare an Environmental Impact Statement (EIS), or, at a minimum, an Environmental Assessment (EA), before the FDA promulgates any final action relating to the reclassification of dental mercury, the classification of encapsulated amalgam alloy and dental mercury, or the issuance of special controls for amalgam alloy.[1]

Mercury, particularly in the methylmercury form, is a potent neurotoxin that can impair neurological development in fetuses and young children and damage the central nervous system of adults.[2] It is toxic, persistent, and bioaccumulative.[3] Mercury may be deposited in water, soils, and air where microorganisms convert mercury into the highly toxic methylmercury, affecting air, water, and soil quality.[4] The United States Environmental Protection Agency

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[1] 42 U.S.C. § 4332(3)(C).

[2] EPA Office of Superfund Remediation and Technology, *Treatment Technologies for Mercury in Soil, Waste, and Water*, at 1-1 (Aug. 2007) (online at www.epa.gov/tio/download/remed/542r07003.pdf).

[3] EPA Mercury Home Page, Environmental Effects (online at epa.gov/mercury/eco.htm) (accessed July 28, 2008).

[4] EPA Mercury Home Page, Basic Information (online at epa.gov/mercury/about.htm (accessed July 28, 2008).

(EPA) has found methylmercury in eagles, otters, and the endangered Florida panthers.[5] Methylmercury's effects on wildlife include death, reduced fertility, slower growth and development, and abnormal behavior that affects chances of survival.[6]

Mercury used in dental devices directly contributes to the global mercury burden. According to one EPA estimate, the United States consumes at least 34 tons of mercury per year for dental preparation and use.[7] Dental mercury waste typically will be captured for recycling, discarded as municipal waste or medical waste, or discharged into the general municipal wastewater system.[8] The amalgam in wastewater from dental offices is the largest direct contributor of mercury to water in the United States, while the incineration of the sewage sludge caught in filters and traps emits mercury pollutants.[9] Mercury from spills, scrap and vacuum pump systems in dental offices release mercury into the air.[10] Cremation vaporizes the mercury in corpses' filings and releases it into the atmosphere.[11] The number of cremations and the average number of fillings per person cremated is expected to increase, magnifying the quantity of mercury released.[12]

A number of states and municipalities have attempted to control the release of mercury from dental offices.[13] The EPA has also recognized the necessity of developing strategies to reduce

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[5] EPA, The Mercury Study Report to Congress, at 3-3, 5-7 (Dec. 1997) (hereinafter the "Mercury Study Report to Congress") (finding that based on reports conducted in EPA's study "methylmercury poisoning sufficiently severe to be fatal to mink and otters can be projected at current mercury exposures in some geographic locations").

[6] EPA Mercury Home Page, Environmental Effects (online at epa.gov/mercury/eco.htm) (accessed July 28, 2008).

[7] US EPA Office of Research and Development, *Mercury Use and Release of Mercury in the United States*, at 13, 34 (Dec. 2002) (EPA/600R-02/104) (online at www.epa.gov/nrmrl/pubs/600r02104/600r02104prel.pdf) (hereinafter the "Mercury Use and Release Report").

[8] *See, generally* Domestic Policy Subcommittee, House Committee on Oversight and Government Reform, Testimony of Michael T. Bender, Director of Mercury Policy Project, *Hearing on Environmental Risks of and Regulatory Response To Mercury Dental Fillings*, (Nov. 14 2007) (hereinafter "Environmental Risks Hearing" and testimony, "M. Bender Testimony").

[9] Mercury Use and Release Report at 6, 35, 36.

[10] Mercury Use and Release Report at 35.

[11] Mercury Use and Release Report at 64-65.

[12] M. Bender Testimony, at 16-17, 18 (testifying that in 2005 between 3.0-3.5 tons of dental mercury emissions may be attributable to human cremation, and comparing this range to the 2002 EPA National Emissions Inventory estimate of 0.3 tons).

[13] Domestic Policy Subcommittee, House Committee on Oversight and Government Reform, Testimony of C. Mark Smith, Co-Chair, New England Governors and Eastern Canadian

mercury discharges from sewage treatment plants by regulating mercury discharges from dental offices.[14] As a result of the significant and underestimated impact of the continued use of dental mercury devices on human health and the environment, this Subcommittee has already conducted two separate hearings on this topic.[15]

Despite these direct, cumulative, long-term, and far-reaching adverse effects on the environment, the FDA has regulated these devices for over twenty years without ever preparing an environmental review to inform its rulemaking.

I. Statutory and Regulatory Framework.

NEPA's purpose is not to mandate specific results, but to require federal agencies to take a "hard look" at the environmental consequences of their actions by following certain procedures during the decision-making process. NEPA's twin aims are to (1) "help public officials make decisions that are based on an understanding of environmental consequences, and take actions that protect, restore, and enhance the environment"[16] and (2) to "insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken."[17] Specifically, NEPA requires a federal agency prepare a detailed EIS in connection with any major federal action that "significantly affects the quality of the human environment."[18] Under the Council of Environmental Quality's (CEQ) implementing regulations, an agency may first prepare an EA to determine whether the environmental impact

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Premiers Mercury Task Force and Deputy Director, Office of Research and Standards, Massachusetts Department of Environmental Protection, *Hearing on Assessing State and Local Regulations to Reduce Dental Mercury Emissions*, (July 8, 2008) (hereinafter the "State and Local Regulations Hearing").

[14] *See* Environmental Protection Administration, *Notice of Availability of Preliminary 2008 Effluent Guidelines Program Plan*, 72,209 Fed. Reg. 61335, at 61347-48 (Oct. 30, 2007) (online at http://www.epa.gov/EPA-WATER/2007/October/Day-30/w21310.htm). (Noting that the "majority of the mercury [pollutants] originates from . . . amalgam used in dental facilities and medical equipment [and other sources], that the "EPA is focusing its evaluation on mercury discharges from the offices and clinics of dentists due to the potential hazard and bioaccumulative properties associated with mercury," and describing numerous efforts at the EPA and at the state and municipal level to create policies to reduce discharges of dental mercury.). In addition, EPA Regions 5 and 8 have published guidance for mitigating the harmful environmental effects of dental mercury discharges. *Id.*; Testimony of Curt McCormick, CWA Consulting Services, LLC, State and Local Regulations Hearing, at 3 (July 8, 2008).

[15] Environmental Risks Hearing; State and Local Regulations Hearing.

[16] 40 C.F.R. § 1500.1(c)

[17] 40 C.F.R § 1500.1(b).

[18] 42 U.S.C. §4332(3)(C).

of the proposed action warrants an EIS.[19] If an EA establishes that the agency's action "may have a significant effect upon the . . . environment, an EIS must be prepared."[20] If the proposed action is found to have no significant effect, the agency must issue a finding of no significant impact (FONSI), and set forth a "convincing statement" of reasons that explain why the agency action will impact the environment no more than insignificantly."[21]

A "categorical exclusion" may exempt certain agency actions from NEPA review. A "categorical exclusion" is defined by CEQ regulations to be:

> a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency in implementation of these regulations ... and for which, therefore, neither an environmental assessment nor an environmental impact statement is required.... Any procedures under this section shall provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect.[22]

II. The FDA's Role

The FDA first proposed classifying dental devices relating to mercury in 1980.[23] In 1987, the FDA finalized its classification of 110 separate dental devices, including dental mercury and amalgam alloy. The FDA stated that its rulemaking in respect of the devices, including dental mercury and amalgam alloy, was subject to a categorical exclusion because it was "of a type that does not individually or cumulatively have a significant impact on the human environment."[24] These regulations classified dental mercury as a class I device, amalgam alloy as a class II device, and due to an inadvertent error, did not separately classify encapsulated amalgam alloy and dental mercury.

In 2002, the FDA proposed to classify dental amalgam and dental mercury separately as a class II device, amend the classification for amalgam alloy by adding special controls, and

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[19] *See* 40 C.F.R. § 1508.9; *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 730 (9th Cir. 2001).

[20] *Id.* (internal quotation marks omitted) (emphasis and alteration in original).

[21] *Id.* (internal quotation marks omitted).

[22] 40 C.F.R. § 1508.42.

[23] Classification of Dental Devices; Development of General Provisions, 45 Fed. Reg. 85962 (to be codified at 21 C.F.R. pt. 872) (proposed Dec. 30, 1980).

[24] Dental Devices; General Provisions and Classifications of 110 Devices. 52 Fed. Reg. 30082 (Aug. 12, 1987) (to be codified at 21.C.F.R. pt. 872).

reclassify dental mercury from a class I to a class II device.[25] In its 2002 notice of proposed rules, the FDA merely restated the proposition that its proposed regulations of mercury-related dental devices was subject to a categorical exclusion because it was "of a type that does not individually or cumulatively have a significant impact on the human environment."[26] On April 28, 2008, the FDA reopened its 2002 proposed rules for consideration and comments. I urge the FDA to now take the requisite "hard look" at the environmental impacts of these devices, and conduct a thorough analysis of this important issue. I also share below several of my specific concerns.

III. The Subcommittee's Concerns.

In conversations with Subcommittee Majority Staff, the FDA contended that there was an administrative record of past agency action that showed that the FDA had properly considered NEPA's requirements when previously regulating mercury-related dental devices. Subcommittee staff requested that the FDA provide: "Documents relating to FDA's review whether NEPA and its implementing regulations mandated or mandates that the FDA conduct either an EA or EIS upon classification or reclassification of mercury-related dental devices, beginning with the 1980 dental mercury device classification and continuing through all subsequent proposed and final dental mercury device classifications and reclassifications."[27] Subcommittee Majority Staff has reviewed the information and documentation provided to the Subcommittee, which amounts to essentially no evidence that the FDA has ever undertaken any real analysis of the environmental effects from the use and regulation of any mercury-related dental devices, much less a "convincing statement" of why their regulatory actions would not significantly impact the environment.

In 1987, the FDA relied on the following categorical exclusion to exclude dental mercury devices from environmental review under NEPA:

> Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because, as a class, these actions will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment. (These actions are listed in paragraphs ... (e) (1) through (3) and

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[25] Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issues of Special Controls for Amalgam Alloy, 67 Fed. Reg. 7620, 7628 (Feb. 20, 2002) (to be codified at 21 C.F.R. pt. 872).

[26] *Id.* The FDA did briefly acknowledge without further consideration that "some Nordic countries, such as Denmark, Finland, Norway, and Sweden have placed legal restriction on dental amalgam for environmental concerns." *Id.*

[27] Letter from Chairman Dennis J. Kucinich to Commissioner Andrew von Eschenbach, Food and Drug Administration (Mar. 5, 2008).

> (5) of this section.) ... Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because these actions meet specific criteria that are intended to ensure that they will not cause significant environmental effects.... The classes of actions that are categorically excluded are as follows:
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> (e) *Devices and electronic products*....
>
> (2) Classification or reclassification of a device under Part 860.[28]

This categorical exclusion was amended in 2005 to categorically exclude any "[c]lassification or reclassification of a device ... including the establishment of special controls, if the action will not result in increases in the existing levels of the device, or changes in intended use of the device or its substitutes."[29] With the 2005 amendments, the FDA has further broadened its already arguably overbroad categorical exclusion.[30] The result is that, contrary to the requirements of NEPA and CEQ regulations, the new regulation allows a broad range of regulatory activities that could have significant effects on the environment to elude any meaningful environmental review.[31]

Furthermore, the FDA has compounded its overly aggressive formulation of its categorical exclusion for mercury-related dental devices by failing to apply the CEQ requirement that an environmental assessment ordinarily excluded under a categorical exclusion be conducted if "extraordinary circumstances" exist that indicate that the proposed action may have a "significant affect" on the quality of the human environment.[32] What significantly affects the

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[28] 21 C.F.R. § 25.24 (1987).

[29] 21 C.F.R. § 25.34(b) (emphasis added).

[30] *See Watson v. Proctor (In re Watson),* 161 F.3d 593, 598 (9th Cir.1998) ("A federal regulation in conflict with a federal statute is *invalid* as a matter of law.") (internal quotations omitted) (emphasis in original).

[31] For example, a deregulation of a device or food substance may not increase the level of its use in the market, nor change the original use of it, but such a deregulation could still have a significant effect on the environment. Likewise, a classification of a device, upward or downward, and the imposition of special controls, could represent a dramatic shift of regulatory policy over these devices and the FDA's ability to mitigate environmental impacts; however, according to the FDA, this type of change in regulating devices would always elude NEPA review.

[32] 21 C.F.R. § 25.21. CEQ's regulations require that "[a]ny procedures [invoked by an agency] under this [categorical exclusion] section *shall provide for extraordinary circumstances* in which a normally excluded action may have a significant environmental effect." 40 C.F.R. § 1508.4 (emphasis added).

environment involves considerations of both "context" and "intensity."[33] A consideration of context "means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality."[34] An evaluation of "intensity," which refers to "the severity of the impact," includes a consideration numerous factors.[35]

All of these factors, as applied to the regulation of mercury-related dental devices, point strongly in favor of requiring a detailed environmental impact statement from the FDA. These regulations for inherently toxic devices affect mercury supply, consumption, storage, and removal. The public's and scientific community's awareness of dental mercury's impacts on the environment, under the current regulatory scheme is growing, and there has been substantial questions raised about the quality and quantity of the data used to assess risk, and specific questions about the areas of harm that have been inadequately addressed.[36] The bioaccumulative

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[33] 40 C.F.R. § 1508.27.

[34] 40 C.F.R. § 1508.27(a).

[35] *See* 40 C.F.R. § 1508.27(b) (listing, among others, as factors for an intensity analysis, "[t]he degree to which the proposed action affects public health or safety," "[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial," "[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks, "[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts," "[t]he degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973." *See also* 21 C.F.R. § 25.21(b) (cross-referencing these factors "as examples of significant impacts.").

[36] *See, e.g.,* EPA Office of Superfund Remediation and Technology, *Treatment Technologies for Mercury in Soil, Waste, and Water*, at 1-6 (Aug. 2007) (online at www.epa.gov/tio/download/remed/542r07003.pdf) ("An approved understanding of the toxic health effects of mercury and its bioacumulative properties has led to greater regulatory control."); *Mercury Study Report to Congress*, at 3-3, 5-7 (stating that in 1995, the estimated 0.64 MG (.7 ton) of mercury emitted from dental preparation and use cited in the report was an "underestimate" because it was derived applying an emission factor only to mercury emission from spills and scrap during dental preparation and use, that the total amount used in the dental industry is 31 Mg (34 tons), and that mercury air emission not accounted for in its estimate of emissions for dental preparation and use was most likely accounted for in the emission estimates from municipal waste combustors, medical waste incinerators, and crematories) (The report did not address mercury discharges from dental offices to publicly owned sewage treatment facilities.); M. Bender Testimony at 18 (testifying to the range of atmospheric emission of dental mercury in 2005 and comparing with the 2002 EPA National Emissions Inventory estimates).

nature of mercury and its persistence in the environment increases the risk of chronic poisoning even if environmental levels of the toxin are low, producing long-term and uncertain health risks associated with these devices. There is also growing attention on the extent of the deleterious health effects on certain subpopulations of humans, aquatic life, birds and mammals.[37]

In the face of these clear legal requirements of NEPA—and the emerging consensus of the harms to the environment from dental mercury—the FDA has maintained in conversation with Majority Staff that the FDA is not required to undertake an EIS or EA because its specific regulatory action here—reclassification and classification of dental mercury devices—merely perpetuates the status quo amount of use of these devices and therefore does not in itself have significant effects. The FDA's position, however, undermines NEPA's purposes and has been expressly rejected by the courts. In *Louisiana v. Lee*,[38] the Court considered the Army Corps of Engineers' argument that its renewal of permits allowing dredging in Louisiana's Lake Pontchartrain would not trigger an environmental review under NEPA because it would merely preserve the status of quo of dredging of the lake.[39] In rejecting this argument, the Court held that "[t]he renewal of these permits will not maintain a status quo, but rather will continue a course of environmental disruption begun years ago."[40] The Court ruled that the damage from dredging was continuing and cumulative and thus the regulatory action of renewing permits, even if it did not lead to more dredging than before, would significantly affect the environment.[41]

Here, the FDA attempts to rely on the same argument discredited in *Lee*. While the proposed classification and reclassification of mercury-related dental devices may arguably maintain some sort of regulatory status quo, it would certainly not maintain an environmental status quo.[42] The continued introduction of mercury into the environment attributable to dental devices would, by dint of its highly toxic, persistent, and bioaccumulating nature, "continue a course of environmental disruption begun years ago."[43] The load of mercury from dental devices in the air, water, and in the food chain can be expected to increase.[44]

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[37] *See, e.g.*, *Mercury Study Report to Congress*, at 3-1 through 3-4 (field data indicating that levels of mercury in panther high enough to cause toxic effects and contribute to decline of endangered animal).

[38] 758 F.2d 1081 (5th Cir. 1985), *cert. denied*, 475 U.S. 1044 (1986)

[39] *Id.*

[40] *Id.* at 1086.

[41] *Id.*

[42] The FDA has, in fact, never established that their proposed regulatory action would have no effect on the total use of these devices.

[43] 758 F.2d at 1086.

[44] Moreover, the FDA would apparently seek to immunize its initial 1987 mercury-related dental device classifications according to the same status quo logic. However, the

Recent case law has reaffirmed that before an agency eschews an EA or EIS required by NEPA, it must take a "hard look" at the environmental consequences of a proposed action, including a consideration of all foreseeable direct and indirect action. After undertaking such a "hard look," an agency must put forth a "convincing statement" of reasons that explain why the agency action will impact the environment no more than insignificantly.[45] Without such an analysis, courts have reversed agency determination as "arbitrary and capricious" pursuant to the Administrative Procedure Act. Here, the FDA's position seems to have been manufactured primarily for the purpose of stymieing this Subcommittee's inquiry. In response to the Subcommittee document request, it was notable how little consideration the FDA has ever given NEPA requirements when classifying mercury-related dental mercury. The documents produced to the Subcommittee added little to the FDA's cursory unexamined invocations of its own categorical exclusions found in its rulemaking. The FDA certainly provided no contemporaneous documentation demonstrating its consideration of the environmental consequences of its rulemaking in 1980, 1987, or 2002; no analysis whether its proposed action met the specific criteria of this categorical exclusion in 1987; no evidence that it was relying on the "status quo" legal theory at any time from 1980 onward; and no acknowledgement more recently that the EPA, states, and localities were scrambling to implement controls on dental mercury in response to the growing body of scientific knowledge that demonstrated the scope and scale of specific harms caused by the introduction of dental mercury into the environment. Instead, it appears that the FDA's position is a post hoc rationalization of the FDA's decision to ignore NEPA's mandates.

I find it difficult to reconcile the goals of NEPA with this interpretation of NEPA that would allow a regulatory scheme to escape environmental review even as it allowed harmful levels of mercury to accumulate in the environment. The FDA has an obligation, and our investigation has revealed that the FDA has not met NEPA's requirements. By preparing an EIS or an EA, the FDA can comply with both the spirit and letter of NEPA.

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implication of this logic is that NEPA would not apply to medical device classifications of pre-existing devices, provided it offers a many years post hoc and unexamined conclusion that the level of the use of the devices has not changed after the classification.

[45] *See Geertson Seed Farms v. Johanns*, 2007 U.S. Dist. LEXIS 14533, No. C 06-01075 (N.D. CA. Feb. 13, 2007); *see also Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1159 (9th Cir. 2006); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211-12 (9th Cir. 1998).

The Oversight and Government Reform Committee is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X, including the FDA.

If you have any questions regarding these comments, please contact Jaron Bourke, Staff Director, at (202) 225-6427.

Sincerely,

Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee

cc: Darrell Issa
Ranking Minority Member