WRITTEN TESTIMONY OF
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before the
DOMESTIC POLICY SUBCOMMITTEE
of the
OVERSIGHT AND GOVERNMENT REFORM COMMITTEE
(Wednesday, November 14, 2007)

I have been asked by the subcommittee to comment on the obligations of the Food and Drug Administration (FDA) under the National Environmental Policy Act (NEPA) in considering the reclassification of dental mercury amalgam under the Medical Device Amendments of 1976. I emphasize at the outset that I am not a lobbyist for any party to this issue or representing any party in any other way. I was asked to testify presumably because of my extensive experience in litigating cases under NEPA.

Section 102 of NEPA, 42 U.S.C. 4332, provides:

> The Congress * * * directs that, to the fullest extent possible: * * * (2) all agencies of the Federal Government shall —
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> (C) include in every recommendation or report or proposals for * * * other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on —
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> (i) the environmental impact of the proposed action,
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> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
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> (iii) alternatives to the proposed action,
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> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
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> (v) any irreversible or irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Thus, NEPA explicitly requires the preparation of an environmental impact statement (an EIS), whenever federal actions significantly affect the quality of the human environment. Numerous cases hold that the human environment includes harm to the health of human beings.

The regulations of the Council on Environment provide that an environmental assessment (an EA) need not be prepared if the proposal "[n]ormally requires an environmental impact statement" or "[n]ormally does not require an environmental impact statement or an environmental assessment (categorical exclusion)." 40 C.F.R. 1501.4(a). The regulations further state that (40 C.F.R. 1508.4):

> "Categorical exclusion" means 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 adapted 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 impact.

Thus, under the CEQ regulations, neither an EIS nor EA is required if the proposed action is properly within a categorical exclusion. The FDA has similar regulations which require an EA for actions within categorical exclusions only "if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment." 21 C.F.R. 25.21.

The FDA has determined that "[c]lassification or reclassification of a device" "are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or EIS * * *." 25 C.F.R. 34(b). This language is considerably less restrictive than the CEQ and FDA's NEPA regulations, 40 C.F.R. 1508.4 and 21 C.F.R. 25.21. 25 C.F.R. 34(b) does not require extraordinary circumstances for the classification or reclassification of a device to require preparation of an EIS or EA.

In any event, the statute is obviously controlling if it is inconsistent with the regulations. The

statute requires an EIS if there is a significant effect on the human environment. The statute does not preclude categorical exclusions for administrative convenience when groups of agency actions may reasonably be determined as ordinarily not causing a significant effect on the human environment. However, if a particular agency action within a categorical exclusion significantly affects the human environment, the statute requires an EIS. Despite the language of 40 C.F.R. 1508.4 and 21 C.F.R. 25.21, there is no need to show that the agency action involves extraordinary circumstances. It is enough that a significant effect on the human environment may occur.

The law is likewise clear that when there is doubt about whether an EIS is required an EIS should be prepared. Thus, the Court of Appeals for the Ninth Circuit has held (*Public Citizen v. Department of Transportation,* 316 F.3d 1002, 1024 (2003)):

> If the environmental effects of a proposed agency action are uncertain, the agency must usually prepare an EIS:
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> > Preparation of an EIS is mandated when uncertainty may be resolved by further collection of data, or where the collection of such data may prevent "speculation on potential. . .effects. The purpose of an EIS is to obviate the need for speculation by insuring that available data are analyzed prior to the implementation of the proposed action.

Accord, *National Parks & Conservation Ass'n v. Babbit,* 241 F.3d 722, 730 (9th Cir. 2001), certiorari denied, 534 U.S. 1104 (2002).

The FDA itself has admitted that an EA is required if there is the possibility of harm to human health or the environment. In promulgating the amendments to its NEPA regulations in 1997, the FDA stated the "FDA will require an EA for any specific action that ordinarily would be

excluded if available evidence establishes that, at the expected level of exposure, a potential exists for a significant effect on the environment" (emphasis added). 62 Fed. Reg. 40570 (1997). Similarly, the FDA stated that its "extraordinary circumstances provision requires that an EA be prepared if a normally excluded action may significantly affect the quality of the human environment" (emphasis added).[1/] *Ibid.* Thus, the Court of Appeal for the Fifth Circuit has held that an EIS is required if "the quality of the human environment *may* be significantly degraded" (emphasis in original). *Louisiana v. Lee*, 758 F.2d 1081, 1084 (5th Cir. 1985).

The FDA determined in its proposed rulemaking in 2002 concerning dental mercury amalgam that (67 Fed. Reg. 7620 (2002)):

> [T]his action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore neither an environmental assessment nor an environmental impact statement is required.

While this language is not entirely clear, it appears that this is merely a restatement of the proposition that the classification or reclassification of medical devices comes within a categorical exclusion.

[1/]Based on these statements, the EPA regulations promulgated by the FDA in 1997 and still in effect state that "extraordinary circumstances justifying at least an EA" include "[a]ctions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment." 21 C.F.R. 25.21(a). The regulation, unlike the preamble, is more restrictive than the statute. NEPA requires only a significant effect on the environment to require an EIS; the FDA regulations require only an EA for potential serious harm to the environment. Again, I emphasize that the statute is controlling.

The proposed rule contains no discussion of possible environmental impacts in contrast to the discussion, albeit brief, of health impacts. Thus, the proposed rule provides no indication that the FDA has even considered the environmental impacts of the reclassification of dental mercury amalgam.

Since I am a lawyer, not a scientist, I will not attempt to analyze the scientific issues as to whether an EIS or, at the very least, an EA is required to analyze the possible harm to human health and the environment. However, the undisputed facts – that mercury is extremely toxic to human health and to aquatic and other life, the substantial contribution of dental mercury amalgam to the total mercury in the environment, the recognition by the American Dental Association of the need for dentists to control the mercury leaving their offices, and the actions of various governmental bodies increasingly imposing restrictions on the use of dental mercury amalgam – strongly support the conclusion that reclassification of dental mercury will significantly affect the quality of the human environment.

In 2005, the FDA modified its NEPA regulations to provide for a categorical exclusion for the "[c]lassification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device." 21 C.F.R. 25.34(b). Again, the regulation is only valid to the extent that it is consistent with NEPA. If the FDA determination would approve continual use of a device significantly affecting the human environment, there is a very strong argument that an EIS or, at the least, an EA is required. It should not matter that the FDA is allowing the continuation of harm that has been already occurring.

Stated differently, the FDA action is significantly affecting the human environment. The

FDA has the authority to deny reclassification, allow reclassification with special conditions, or allow reclassification without conditions. These special conditions as to dental mercury amalgam could include prohibition of, or cautions against, use for children and/or pregnant women, and requirements to discuss with patients the presence of mercury in amalgams and alternatives to such amalgams,

Section 102(C)(iii) of NEPA, 42 U.S..C 4332(C)(iii), requires that EIS's consider "alternatives to the proposed action." The courts have held that this requirement is the very heart of the NEPA process. The choice FDA makes between the alternatives before it obviously will affect what harm from dental mercury amalgam will continue.

In addition, it is likely that the harm from dental mercury amalgam will increase if the FDA permits its continued use without special conditions. For example, since the number of Americans is i[illegible] ore mercury amalgam use is likely to occur, thereby increasing the amount of mercury [illegible]ged into the environment. Even if use of mercury amalgam does not increase, further discharges are likely to cause a build-up of mercury when added to mercury already in the environment. Thus, even if the mercury amalgam is not used more, the harm to the environment is likely to increase. In such circumstances, an EIS, or at the least, an EIS is required.