ARGUMENT SCHEDULED -- SEPTEMBER 17, 2001

Civ. No. 00-5364

IN THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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JIM J. TOZZI, *et al.*,

Plaintiffs, Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants, Appellees.

_____

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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APPELLANTS' REPLY

_____

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SUMMARY OF ARGUMENT

Plaintiffs have standing because they had a reasonable concern of harm at the commencement of this action and continue to have such concerns. Appellees'[1] argument that the *RoC* is not judicially reviewable has been rejected by the only court to consider it, and Defendants' new position on the criteria is also reviewable "agency action" in any event. That position is contrary to the plain meaning of the rule, is contradicted by contemporaneous evidence of agency intent, and is entitled to no deference. Defendants never publicly announced and explained their new position, and the nonpublic, noncontemporaneous, "contentions" Defendants cite do not alter this fact.

ARGUMENT

I. The Agency Has Misstated the Record.

The agency first takes a number of liberties with the record in reciting the factual background. The minutes of the June 29, 1995 NTP Board meeting plainly indicate that Dr. Barrett of NIEHS did not "*state*" (Opp. Br. at 6.) that a substance could be listed as a known human carcinogen absent sufficient epidemiologic data. Rather, he merely "*contended*" that such a listing was possible. R. 7 at 5. The agency's assertion that this isolated "contention" from one staff scientist *"clearly shows [what] drafters of the*

[1]Appellants refer to Appellees collectively herein, unless otherwise specified, as "Defendants", "the agency" or "NTP".

revised criteria intended" stretches the record beyond the breaking point. Id. at 30. Similarly misleading is the agency's account of the preceding suggestion by Dr. Lucier in the same minutes, where he noted, "*a point of discussion might be* whether there could be compelling mechanistic data. . . ." R. 7 at 5. This is hardly a public announcement of a new DHHS policy. The three *ad hoc* working groups reviewing the listing criteria had *voted down* proposals to modify the known category criteria in the manner Defendants now suggest was actually adopted (Def. P.I. Opp. Exh. 4 at 3 and "Summary Report" Group 2 at 2, 3), and nothing in the subsequent NTP Board meeting minutes "states", or even implies, a decision by NTP to disregard the working groups' votes.

Dr. Lucier also did not opine about the revised criteria *"[s]hortly after"* they were promulgated (Opp. Br. at 7, 34), but rather *thirteen months after* their publication, after he learned that Mr. Tozzi and other commenters were contesting NTP's reliance on mechanistic data to justify the upgraded dioxin listing. The agency's eagerness to characterize Dr. Lucier's remarks as having been made nearer in time to the promulgation of the revised criteria does suggest, however, that Defendants understand the rule against deference to *post hoc* agency statements, as set forth in Gardebring v. Jenkins, 485 U.S. 415, 430 (1988), Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168-69 (1962), and other cases.

II. Plaintiffs Satisfy the Requirements for Standing.

The district court correctly held that Plaintiff Brevet had standing to challenge the

dioxin listing based on the reasonable concern of threatened harm expressed in the affidavit of Brevet's President, Charles Brewer. Mem. Op. at 6-8. The district court's conclusion was in accord with Friends of the Earth v. Laidlaw Envtl. Servs. (TOC), Inc. 528 U.S. 167, 169 (2000) (standing supported by affidavits expressing "reasonable concerns about the effects of" the threatened harm), and was fully supported by the evidence Plaintiffs submitted.[2]

Brevet manufactures disposable plastic connectors for use with polyvinyl chloride ("PVC") tubing and surgical units used during open-heart surgery. Brevet's flexible connectors are designed to connect exclusively to flexible PVC vinyl tubing. Pl. S.J. Mem. Exh. 1 ("Brewer Aff.") at ¶ 5. Over 95 percent of Brevet's sales depend upon the continued use of flexible PVC tubing in the medical equipment industry. Brewer Aff. at ¶¶ 5, 10(a).

During the year leading up to Brevet's entry into this lawsuit, three major municipalities in Brevet's home state of California had passed forceful resolutions calling for the phase out and eventual elimination of PVC plastic products. These resolutions

[2]Appellants addressed the standing of the restaurant Plaintiffs in their Brief (at 47-51) and focus herein primarily on the standing of Plaintiff Brevet. As previously noted, once the Court concludes that any *one* Plaintiff has standing, the Court need not engage in a separate standing analysis with respect to other Plaintiffs. Watt v. Energy Action Educ. Found., 454 U.S. 151, 160 (1981).

were all based, in part, on just a *preliminary* conclusion of one *RoC* review panel regarding the carcinogenicity of dioxin, a substance allegedly released into the environment during incineration of PVC medical equipment. See Am. Compl. Exhs. 5 at ¶ 3 & n. 3, 6 at ¶ 3 & n. 3, and 6A at p.2, ¶ 3 & n. 3. Environmental activist groups had taken direct aim at the PVC industry, including medical equipment companies such as Brevet. Groups including the "Zero Dioxin Alliance", had announced their intention to "build on the victories" of the three municipal resolutions above. See Pl. S.J. Mem. Exh. 4 at p. 3 of 4 (announcing meeting of Zero Dioxin Alliance in Oakland, California, on February 23, 2000). They were also keeping a watchful eye on the dioxin listing proposed for the 9th RoC. See Pl. S.J. Mem. Exh. 5 at p. 15 of 59.

In addition to identifying dioxin as a known human carcinogen, the proposed (now final) *9th RoC* listing referred to "hospital wastes" as one source of dioxin releases. Supp. R. at III-58B. It was therefore reasonable for Brevet to be concerned that these activist groups would trumpet the new dioxin listing as a formal endorsement of their campaign against PVC medical equipment. See Pl. S.J. Mem. Exh. 6 (dioxin activist paper describing "medical waste problem"). The proclamations Brevet feared have come to pass, and the threat of harm from NTP's final dioxin listing, about which Plaintiffs were reasonably concerned, continues to this day.[3]

[3]The agency argues that this matter arguably has become moot since publication of the dioxin addendum to the *9th RoC* in January of this year. Opp. Br. at 23 n. 4. Because the nature of the harm to Plaintiffs is continuing, however, the agency's mootness argument clearly fails.

Moreau v. FERC, 982 F.2d 556, 566 (D.C. Cir. 1993) (case not mooted where pipeline, although already in operation, continued to harm property owners' aesthetic interests); see also Calderon v. Moore 518 U.S. 149, 150 (1996) ("The available remedy, however, does not need to be 'fully satisfactory' to avoid mootness.... [E]ven the availability of a 'partial remedy' is 'sufficient to prevent [a] case from being moot.'") (quoting Church of Scientology of California v. United States, 506 U.S. 9, 13 (1992)). An order from this Court directing the agency to retract its January 19, 2001 addendum and to reinstate dioxin in the reasonably anticipated category would, like the January addendum itself, be widely publicized and would significantly counter the efforts of anti-PVC activists. Although an agency statement once made cannot be fully taken back, a publicized retraction and correction can be very significant. Ironically, the case the agency cites in support of its mootness argument not only held that the matter before the appeals court was *not* moot, but makes this very point. See Church of Scientology, 506 U.S. at 12-13 ("While a court may not be able to return the parties to the *status quo ante* -- there is nothing a court can do to withdraw all knowledge or information . . . -- a court can fashion *some* form of meaningful relief in circumstances such as these.").

In challenging Plaintiffs to produce updated evidence detailing how the threatened harm to Plaintiffs has played out since publication of the new dioxin listing in January, (see Opp. Br. at 23), the agency seeks to impose upon Plaintiffs a duty that does not exist. If the Court concludes that Brevet had a reasonable concern of harm at the time it entered the suit, then the district court's finding of standing should be affirmed. The cases are clear that standing "is assessed 'at the time the action commences'". Advanced Mgmt. Tech., Inc. v. FAA, 211 F.2d 3d 633, 636 (D.C. Cir. 2000) (quoting Friends of the Earth); Natural Law Party of United States v. FEC, 111 F. Supp. 2d 33, 40 (D.D.C. 2000); see also Becker v. FEC, 230 F.3d 381, 387 (1st Cir. 2000), *cert. denied*, 121 S.Ct. 1733 (2001); Park v. Forest Serv., 205 F.3d 1034, 1037 (8th Cir. 2000).

Notwithstanding this principle, however, Appellants are attaching to their Reply several items demonstrating that the threat of harm to Plaintiffs continues.[4] These items illustrate the national publicity the agency's January 2001 dioxin addendum received, including coverage on the prominent *New York Times*/Reuters newswire and in newspapers from Utah to West Virginia to Rhode Island. See Exhs. 1, 2, 3, 4, 6. The evidence also shows that the new listing has been hailed by activist groups, just as Plaintiffs predicted, in furtherance of various anti-PVC and other initiatives. See Exhs. 5, 8. Hospitals in at least one state (Maine) have now cited the "known human carcinogen" finding as a basis for reducing purchases of PVC medical supplies. Exh. 7. The group

[4]Plaintiffs filed a consent motion for leave to supplement the record on July 2, 2001.

Healthcare Without Harm has pointed to the NTP dioxin reclassification, and the Maine hospital group's resulting anti-PVC decision, in support of further calls for a "phaseout" of PVC plastic. Exh. 8.

A. Injury-in-Fact

With respect to the injury-in-fact element for standing, Plaintiffs need not demonstrate that the harm threatened is *certain* to occur. As noted above, mere "reasonable concerns about the effects of" the threatened harm is sufficient. Friends of the Earth, *supra*, 528 U.S. at 169. Thus, even *potential* harm is enough to satisfy the element of injury-in-fact. See Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1234-35 (D.C. Cir. 1996) (increased risk of wildfire from certain logging practices constituted injury-in-fact); Village of Elk Grove Village v. Evans, 997 F.2d 328, 329 (7th Cir. 1993) ("even a small probability of injury is sufficient to create a case or controversy") (citing Pennell v. San Jose, 485 U.S. 1 (1988)). As discussed below, Plaintiffs clearly satisfy the requirement of injury-in-fact.

The agency criticizes Plaintiffs' reference to the three anti-PVC municipal resolutions adopted in Brevet's home state. Characterizing the harm to Brevet as "a game of pure guesswork", the agency argues that because the San Francisco area municipalities have yet to "act in a manner with consequence", the three resolutions should carry no weight in the standing analysis. This is not true. These initiatives fairly typify one kind of very real market threat that justifies Brevet's reasonable concerns. Regardless of their

"regulatory" impact, the resolutions clearly convey these municipalities' intentions to reduce, near-term, their PVC medical device purchases, including purchases of Brevet's products. See Am. Compl. Exhs. 5 at 3, 6 at 3 and 6A at 5-6. This is more than sufficient reason for Brevet to be concerned about NTP's new report.[5] The agency's citation to Simon v. Eastern Kentucky Welfare Rights Org., 426 U.S. 26, 45 (1976), is thus misplaced.[6] Here, the city hospitals would have no choice but to follow local authorities' anti-PVC purchasing decisions. In any event, Simon predates by some 25 years the current "reasonable concern" standard for injury-in-fact, as enunciated in Friends of the Earth.[7]

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[5]Appellants' citation to Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985), is puzzling. That case concerned a motion for a preliminary stay and addressed the showing necessary for irreparable harm, not the showing necessary to support standing. The case also had nothing to do with activist pressures, municipal initiatives or other so-called "political outcome[s]".

[6]In Simon, the respondents challenged an IRS revenue ruling that granted favorable tax treatment to nonprofit hospitals that offered only emergency room services to the poor. The respondents had argued that the revenue ruling "'*encouraged*' hospitals to deny services to indigents." 426 U.S. at 42 (emphasis added). The Court held that the chain of causation was too attenuated, noting, "it is just as plausible that the hospitals to which respondents may apply for service would elect to forgo favorable tax treatment to avoid the undetermined financial drain of an increase in the level of uncompensated services." 426 U.S. at 42-43.

[7]The agency's citations on injury-in-fact to two other decisions that pre-date Friends of the Earth are similarly unpersuasive. In Whitmore v. Arkansas, 495 U.S. 149 (1990), the Court ruled against a death row inmate's claims of injury allegedly arising from a second death row inmate's failure to seek appeal. The plaintiff inmate had stabbed his own victim 10 times, however, cut her throat, and carved an X in her face, and the Court thus found that any effect on the plaintiff's own death sentence from the failure to add the other killer's crimes to a general "data base" that was used for comparison purposes in sentencing was too speculative to grant the plaintiff standing. 495 U.S. at 157. In Defenders of Wildlife v. Lujan, 504 U.S. 555 (1992), the Court held that environmentalists' statements that they hoped to return to certain places in the

world to observe endangered species allegedly threatened by U.S. agency projects did not constitute injury in fact. 504 U.S. at 563-64. Here, the threat to Plaintiffs' sales from the inflammatory statements in the *9th RoC* is far more imminent -- and more fairly a basis for "reasonable concern" -- than was the remote harm alleged in either of those cases.

The *9th RoC* dioxin listing has resulted, and will continue to result, in enormous public and political pressure for municipalities and other entities to take action against the use of PVC medical products such as Brevet's and will also put pressure on suppliers and users to de-select Brevet's products. Defendants' challenge to the reasonableness of Brevet's concerns also cannot stand in light of the "Stop Dioxin Campaign" and other activist movements in Brevet's home state calling for the complete elimination of PVC. See Pl. S.J. Mem. Exhs. 4, 5, 6.

The Supreme Court has recognized that where events similar to those that threaten the alleged harm have taken place in the past, the finding of requisite injury to support standing in a "three-party" threatened injury case is more easily justified. See Blum v. Yaretsky, 457 U.S. 991, 1001 (1982) ("in light of similar determinations already made by the committee of physicians chosen to make such assessments . . . threat [of injury was] quite realistic"). Where the existence of injury is at issue in the three-party case, the question "usually turns on a determination of 'how likely it is that the third party's response to the challenged governmental action will injure the plaintiff *at all*'". Natural Resources Defense Council, Inc. v. Jamison, 787 F. Supp. 231, 234 (D.D.C. 1990) (holding environmental group had standing to challenge rules affecting leasing and mining of federally owned coal) (emphasis in original) (quoting Wilderness Soc'y v. Griles, 824 F.2d 4, 12 (D.C. Cir. 1987)). Thus, "even a minuscule pecuniary stake of the litigant" may be sufficient to satisfy the standing requirements where larger values (such

as an agency's adherence to its own rules) are at issue. American Bankers Ins. Group v. Board of Governors of the Fed. Reserve Sys., 3 F. Supp. 2d 37, 41 (D.D.C. 1998) (quoting National Automatic Laundry and Cleaning Council v. Schultz, 443 F.2d 689 (D.C. Cir. 1971)).

Here, Brevet submitted evidence that it had already lost some customers due to concerns over the nexus between Brevet's product and alleged dioxin hazards. Shortly before the amended complaint was filed, one of Brevet's customers, Baxter International, under pressure from shareholder groups and activist organizations, announced its intention to develop and introduce intravenous systems that do not use PVC tubing. See Pl. S.J. Mem. Exh. 1 (("Brewer Aff.") at ¶ 8; Pl. S.J. Mem. Exh. 7. Other major medical equipment purchasers have also indicated they would follow Baxter's lead and shift away from PVC tubing. Pl. S.J. Mem. Exh. 8.[8] The district court correctly held that this

[8]In discussing the Tenet Healthcare press release attached to the Brewer affidavit, Defendants state that Brevet has failed to allege that it sold PVC products to Tenet. Opp. Br. at 20 n. 2. But this is not the point, of course. The same press release also identifies *other* companies that have moved away from PVC products because of their concern over dioxin, and, as Brevet clearly has alleged, "Some of the other companies referenced in this Tenet press release

evidence supported Brevet's reasonable concerns over harm from the upgraded dioxin listing. Mem. Op. at 6.[9]

. . . include major customers of Brevet's." Brewer Aff. at ¶ 8.

[9]The agency cites no authority for its assertion that Appellants were required to establish "with reasonable certainty which of Brevet's customers will stop buying PVC plastic". Opp. Br. at 18. Such a detailed showing is not required. Instead, Brevet was required merely to demonstrate a "reasonable concern" of harm. Friends of the Earth, *supra*, 528 U.S. at 169.

B. Causation

Plaintiffs also satisfy the requirement that the injury be "fairly traceable" to the conduct of the defendant.[10] The agency cites no authority for its remarkable claim that standing is precluded where the injury alleged is "the result of conduct by a third party not before the court." Opp. Br. at 16. This Court's precedent clearly demonstrates that the opposite is true. See, e.g., National Wildlife Federation v. Hodel, 839 F.2d 694, 705-06 (D.C. Cir. 1988) ("mere indirectness of causation is no barrier to standing, and thus, an

[10]This requirement is not equivalent to the tort requirement of causation. National Resources Defense Council v. Watkins, 954 F.2d 974, 980 n.7 (4th Cir. 1992); Block v. Meese, 793 F.2d 1303, 1309 (D.C. Cir. 1986) (noting that while government's argument on causation might have relevance to tort action, "it is irrelevant to the question of core, constitutional injury-in-fact, which requires no more than *de facto* causality"). In order to demonstrate that they are more than "concerned bystanders", plaintiffs need only show that there is a "substantial likelihood" that defendant's conduct caused, or is likely to cause, plaintiff's harm. See also Public Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals, Inc., 913 F.2d 64, 72 (3d Cir. 1990) ("requirement that plaintiff's injuries be 'fairly traceable' to the defendant's conduct does not mean that plaintiffs must show to a scientific certainty that defendant's effluent and defendant's effluent alone, caused the precise harm suffered by the plaintiffs") (citing Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59, 78 (1978)), *cert. denied*, 498 U.S. 1109 (1991).

injury worked on one party by another through a third party intermediary may suffice"); Public Citizen v. Lockheed Aircraft Corporation, 565 F.2d 708, 717 n. 31 (D.C. Cir. 1977) ("We are concerned here not with the length of the chain of causation, but on the plausibility of the links that comprise the chain.")

Cases finding standing on the basis of intermediate acts of third parties include situations, such as this case, where the harm arises from a strong public reaction to administrative conduct. In a glaring omission, the agency's brief avoids any reference to Block v. Meese, 793 F.2d 1303 (D.C. Cir.), *cert. denied*, 478 U.S. 1021 (1986), one of the principal cases upon which the lower court premised its conclusion that Plaintiff Brevet had standing. Mem. Op. at 7-8. In Block, the court held that the plaintiff had standing to challenge a Department of Justice classification of the plaintiff's films as political propaganda, even though the alleged injury occurred only through "irrational" public perception of the label. 793 F.2d at 1309. The same kind of "irrational" public perception is at issue here.[11]

[11]For additional discussion of third party causation, see International Union of United Auto., Aerospace & Agric. Implement Workers of Am.. v. Brock, 783 F.2d 237, 247 (D.C. Cir. 1986) (holding unions satisfied "fairly traceable" requirement in challenge to Department of Labor decision effectively modifying an intermediary employer's legal reporting obligations),

and National Comm. to Preserve Social Security v. Bowen, 735 F. Supp. 1069, 1081 (D.D.C. 1990) (holding presence of employer as intermediary in causation chain did not preclude standing in suit against Social Security Administration).

The agency quotes United Transp. Union v. Interstate Commerce Comm'n, 891 F.2d 908, 912 (D.C. Cir. 1989), for the proposition that a court "*may* reject as overly speculative" future injuries that result from the acts of third parties. Opp. Br. at 19 (emphasis added). Appellants, of course, do not dispute the Court's authority to reject *truly* speculative claims. In its next breath, however, the court in United Transp. Union cautioned, "On the other hand, we are much less free to reject allegations of existing conditions, of prior or ongoing actions (*including intent*)." 891 F.2d at 912-13 (emphasis added). Here, Plaintiffs provided clear evidence both of prior customer losses and of ongoing concern and intent among Brevet's *current* customers. Plaintiffs also documented the *existing* intent of activist organizations to eliminate PVC products.

The agency's recitation of the many ways in which dioxin has already been regulated (Opp. Br. at 22-23) only serves to highlight PVC and certain foods as two of the key remaining sources of dioxin exposure. Appellants' products, in effect, are largely the "final frontiers" for anti-dioxin activism, and the *9th RoC* therefore will direct even more critical attention to these products.[10]

C. Redressability

Defendants argue briefly that the harm from the new listing could not be redressed

[10]Defendants make the astonishing and clearly false statement, "Congress did not intend that the RoC . . . alter behavior. . . ." Opp. Br. at 25. In fact, this is precisely what Congress intended. See H.R. Rep. No. 95-1192, 95th Cong., 2d Sess. (1978) at 22 (Mot. Dismiss Exh. 1 at 22) ("a considerable amount of cancer can be prevented or at least detected early if more people become aware. . . .")

by order of the Court. The Court clearly may order that the new listing be withdrawn, however, and, as the district court found, such an order "might stave off the effects of the attack on dioxin for a time." Mem. Op. at 8. Defendants' additional discussion on this point is mere repetition of their injury and causation arguments.

Finally, if Brevet does not have standing to challenge the disputed dioxin listing then arguably no one does. To deny standing to all possible plaintiffs would be to hold that the *RoC* is not judicially reviewable at all. As discussed below, such a conclusion is contrary to principles of APA interpretation and to specific precedent addressing the reviewability of the *RoC*.

III. There is Reviewable Agency Action in This Case.

The district court reached the merits of Plaintiffs' APA section 706 argument and, by implication, rejected the agency's contention that there was no "agency action" under APA section 704 for the court to review. This Court should do the same. There is a strong presumption under the APA in favor of judicial review. Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 670 (1986). That strong presumption may be overcome only upon a showing of clear and convincing evidence of a contrary legislative intent. Traynor v. Turnage, 485 U.S. 535, 542 (1988) (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 141 (1967)). Decisions regarding reviewability of agency actions are particularly fact-specific and dependent on the agency action at issue. See Industrial Safety Equip. Ass'n, Inc. v. EPA, 837 F. 2d 1115, 1117 (D.C. Cir. 1988) (noting that

statutory categories of agency action "are imprecise" and determinations of reviewable agency action are made on a "case-by-case basis").

Given that the question of reviewability is so fact-specific, it is particularly significant that the only court to consider the reviewability of the *RoC* itself has held that that the report is reviewable agency action. See Synthetic Organic Chem. Mfrs. Ass'n v. Secretary, DHHS, 720 F. Supp. 1244, 1249 (W.D. La. 1989) ("SOCMA"). The court in SOCMA ruled, first, "The Secretary's adoption of the Classification Procedures and Criteria fits well within the rubric of reviewable 'agency action.'" Id. at 1249. The court then specifically held that the issuance of the *RoC* "is agency action even though it is informational and imposes no sanctions or obligations." Id. at 1249-50 (quoting Dow Chem., USA v. Consumer Product Safety Comm'n, 459 F. Supp. 378, 386-87 (W.D. La. 1978) ("'moral suasion' is a considerably potent force in our society")). Finally, the SOCMA court rejected the agency's argument that the Secretary's listing decisions were committed to agency discretion and thus beyond review. Id. at 1250.

The SOCMA holdings are well in keeping with the Supreme Court precedent favoring judicial review discussed above. As the SOCMA court explained "the Supreme Court has recognized that the term 'agency action' is to be interpreted expansively, as it brings together previously defined terms . . . to assure the complete coverage of every form of agency power, proceeding, action or inaction." Id. at 1249 (quoting FTC v. Standard Oil Co. of Calif. 449 U.S. 232, 238 n. 7 (1980)). The agency has made no

attempt to explain why the reasoning in SOCMA, the case most squarely on point, is in any way deficient. Defendants' conclusory dismissal of this crucial precedent (Opp. Br. at 27 n. 6) therefore should not dissuade the Court from reviewing and redressing the manifest errors in the dioxin review and listing.

The cases upon which the agency relies, where courts addressed the reviewability of *other* agency actions, are readily distinguishable. First, Defendants resurrect their previously discarded citation to Industrial Safety Equip. Ass'n, Inc. v. EPA, 837 F.2d 1115 (D.C. Cir. 1988), to argue that an agency's issuance of a so-called "informational" document is beyond the scope of APA review. Opp. Br. at 24.[11] The Industrial Safety case, however, addressed contentions that EPA had failed to follow proper notice-and-comment procedures for "substantive" or "legislative" rules under APA section 553. See id., 837 F.2d at 1116, 1119, 1121 & n.11. Plaintiffs in that case did not challenge the agency's action as "arbitrary and capricious" under APA section 706. Unlike the Plaintiffs here, the plaintiffs in that case also did not allege that an agency interpretation of its rules resulting in dissemination of damaging information, and the information itself, were "false". Id., 837 F.2d at 1122. Plaintiffs here are not challenging the agency's failure to follow notice-and-comment procedures. Instead Plaintiffs are challenging

[11]The agency first cited Industrial Safety Equip. in its July 20, 1999 motion to dismiss. Plaintiffs distinguished the case in opposing the agency's motion (Pl. Opp. at 33-34 & n. 11), and the agency failed to cite it again. Although the district court did not expressly address the case, the court rejected the agency's reviewability argument (Mem. Op. at 9) and thus held that issuance of the upgraded dioxin listing was reviewable agency action.

agency actions on the basis that such actions are arbitrary and capricious, or "false". The case is therefore clearly inapposite.[12]

[12]The court in Industrial Safety stated that "[b]ecause ISEA does not attack the Guide as false or misleading, we need not decide the question left open by this court in *Impro Products, Inc. v. Block*, 722 F.2d 845, 849 (D.C. Cir. 1983), whether the intentional dissemination of false information constitutes agency action subject to review." 837 F.2d at 1121. In Impro Products, the court cast doubt on the continued validity of its 1948 decision in Hearst Radio v. FCC, 167 F.2d 255 (D.C. Cir. 1948), which was the basis for questioning the reviewability of an agency's informational action not challenged as false or misleading. The Impro Products court stated, "we believe that *Hearst Radio* may no longer be viable precedent; we are therefore disinclined to find that no 'agency action' has taken place." 722 F.2d at 849. The basis for this belief was in part the Supreme Court's decision in FTC v. Standard Oil Co. of California, 449 U.S. 232 (1980), in which the Court found that agency issuance of an administrative complaint, without adjudication of the complaint, was reviewable "agency action". The Supreme Court quoted language from the legislative history of the APA stating that the definition of "agency action" was intended "to assure the complete coverage of every form of agency power, proceeding, action, or inaction."

449 U.S. at 238 (quoting S. Doc. No. 248, 79th Cong., 2d Sess., 255 (1946)). The Impro Products court also noted that lower federal courts since 1948 had developed a more expansive interpretation of "agency action" than the one suggested by Hearst Radio. 722 F.2d at 849. The court particularly questioned the continued validity of Hearst Radio in a case -- such as the present one -- "in which there is specific statutory authorization for the dissemination of information." Id. As recently as February of this year, the Supreme Court reiterated its position from Standard Oil that the term "agency action" in the APA "is meant to cover every manner in which an agency may exercise its power." American Trucking Ass'ns v. Whitman, 531 U.S. 457, ___, 121 S.Ct. 903, 915 (2001) (holding agency statement of policy was final agency action).

The agency mistakenly implies that an "agency action" must be in the form of a rule or regulation before it can have "regulatory effect" (Opp. Br. at 4, 14, 16) and become subject to judicial review. However, the APA definition of "agency action" states that it "*includes*" a rule, order, etc. 5 U.S.C. § 551(13). This necessarily means that the definition encompasses actions *other than* merely a rule, order, license and so on, otherwise the word "includes" would be mere surplusage. This court and others have interpreted the term "includes" in a statutory definition as a term of enlargement rather than of limitation. American Fed. of Television and Radio Artists, Washington-Baltimore Local, AFL-CIO v. National Labor Relations Bd., 462 F.2d 887, 889 (D.C. Cir. 1972); Federal Trade Comm'n v. MTK Marketing, Inc., 149 F.3d 1036, 1040 (9th Cir. 1998); see also Toro Co. v. White Consolidated Indus., Inc., 199 F.3d 1295, 1300 (9th Cir. 1999) (interpretation of patent).[13]

Moreover, Plaintiffs here are challenging as arbitrary and capricious not only the agency's final listing *decision*, but also its final *policy* for interpreting the listing criteria. Am. Compl. ¶ 4. The agency's new position on the known criteria is itself a "statement . . . designed to implement, interpret, or prescribe . . . policy" and is thus a "rule" under

[13]The court in Industrial Safety strayed from the statute by omitting the word "includes" in the APA definition it cited. See Industrial Safety, *supra*, 837 F.2d at 1117. The court thus unnecessarily narrowed the definition of reviewable "agency action" under sections 702 and 704. In any event, as noted in the text, that case is readily distinguishable on other grounds.

the APA. 5 U.S.C. § 551(4). As such, it falls within the explicit wording of the APA definition of "agency action". 5 U.S.C. § 551(13).

The agency cites two cases in which courts considered the reviewability of agency action under the Resource Conservation and Recovery Act. In both American Portland Cement Alliance v. EPA, 101 F.3d 772 (D.C. Cir. 1996), and American Petroleum Inst. v. EPA, 216 F.3d 50 (D.C. Cir. 2000), however, the court's review authority was expressly limited by RCRA, 42 U.S.C. § 7006(a)(1), a statue wholly inapplicable here. The RCRA provision, by its plain terms, provides for judicial review of only three types of EPA actions: (i) promulgation of final regulations, (ii) promulgation of requirements, and (iii) denial of petitions for promulgation, amendment, or repeal of regulations. American Portland Cement, 101 F.3d at 775; American Petroleum Inst., 216 F.3d at 67. Because none of these three statutory categories included the hazardous waste determination on cement kiln dust at issue in American Portland Cement or EPA's inaction on coke fines at issue in American Petroleum Inst., the court in each case held that it lacked jurisdiction under RCRA.

Here, there is no comparable statutory provision circumscribing the Court's APA review authority. The APA allows judicial review of "agency action", which has a broader meaning than merely the promulgation of final regulations or requirements, or the denial of petitions for promulgation, amendment, or repeal of regulations. See 5 U.S.C. § 551(13) ("'agency action' *includes* the whole or part of an agency rule. . . .") (emphasis

added). Appellees' invocation of RCRA precedent is therefore unpersuasive.

IV. The Court Should Reject the Agency's Arguments on the Merits.

A. The Agency's *Post Hoc* Position on the Criteria Is Not Entitled to Deference.

The agency fails to discuss, or even cite, perhaps the most important precedent in this litigation, Gardebring v. Jenkins, 485 U.S. 415 (1988), and S.G. Loewendick & Sons, Inc. v. Reich, 70 F.3d 1291, 1294 (D.C. Cir. 1995) (quoting Gardebring). Gardebring held that a court is not to accord an agency's reading of its own rule deference where an alternative reading is compelled by either (i) "the regulation's plain language", or (ii) "other indications of the Secretary's intent at the time of the regulation's promulgation." Gardebring, 485 U.S. at 430. The concept of a court making an initial assessment of whether deference to an agency's interpretation of its own rule is appropriate, however, seems to have eluded the agency.

This is no surprise given Defendants' misunderstanding of such critical terms in Gardebring as "contemporaneous" and "Secretary's intent". Thus, Dr. Lucier's statement more than thirteen months after promulgation of the revised criteria is not "shortly after" adoption of the criteria, as the agency asserts (Opp. Br. at 7, 34), and the "contentions" of other *subordinates* such as Dr. Barrett (see Opp. Br. at 6, 30) hardly supersede the clear statement approved by the *Secretary* and released on the very day the revised criteria were issued.

In addition to the *Federal Register* notice itself, the only documents in the record

dating from around the time the revised criteria were issued both support Appellants' reading of the criteria. The fact that the district court failed to address either the September 26, 1996 HHS press release or the August 1996 *Environmental Health Perspectives* article is hardly "beside the point", as the agency contends.[14] Opp. Br. at 37. For the court automatically to assume that the agency was entitled to substantial deference in its new position on the criteria in the face of such evidence was clear error.

The agency's unsupported assertion (Opp. Br. at 36) that the *Environmental Health Perspectives* article "did not receive Department clearance" is plainly contradicted by the record. Secretary Shalala herself approved the issuance of such an article on September 13, 1996. P.I. App. Exh. 8 at 4. It is ironic that the agency would go to such lengths to deny that "Department clearance" was granted for an article which the agency now claims supports its position.

B. The Agency's Interpretation Is Contrary to the Plain Meaning of the Criteria.

[14]Defendants' transparent attempts to belittle the Departmental press release as a "newsletter" and "staff-authored" are amusing. As the document itself plainly states, however, it was a "Press Release", and it was formally issued by the Department of Health and Human Services -- not by the subsidiary agency, NIEHS -- on the very day the revised criteria were published. The document unquestionably speaks for "the Secretary", who authorized its issuance. P.I. App. Exh. 8 at 3-4.

Defendants contend that Plaintiffs' argument hinges on the final descriptive paragraph applying to the reasonably anticipated category only. This is not so. Plaintiffs have argued that, even if the paragraph does apply to both categories, mere use of the term "relevant information" in that paragraph does not put the public on notice of a substantive change to the known criteria, but rather refers merely to what is "relevant" under the previously stated definition for "known". This reading is supported by the explicit framework of the September 26, 1996 *Federal Register* notice, which carefully points out the changes being made to the known criteria. Again, the final paragraph does not state that it is adding anything to the known criteria.

The agency protests that since September 1996 -- or "day one" (Opp. Br. at 36) -- it has always interpreted "studies in humans" to include mechanistic data. Yet it cannot point to a single instance prior to the current dioxin listing, including any listing from the 1998 *8th RoC*, where the agency relied on mechanistic data to compensate for less than sufficient epidemiologic data.[15]

Defendants note that the new references to mechanistic data were placed in the final descriptive paragraph (Opp. Br. at 5), but they fail to point out that references to mechanistic data were also added to the "reasonably anticipated" criteria, *and only to*

[15]Defendants dismiss the amici as offering merely an alternative opinion on the strength of the scientific evidence. Opp. Br. at 28. The more important point amici make is that the term "in humans" is recognized in the scientific community as meaning epidemiologic data only, not some ill-defined "combination" of epidemiologic data and "mechanistic information".

those criteria. If the agency's interpretation is correct, why were references to mechanistic data not also added to the known criteria?

C. The Agency's Position Will Blur the Distinction Between the Known and the Reasonably Anticipated Listing Categories.

Defendants have no real answer to Appellants' argument that the agency's position on the final descriptive paragraph would permit the placement of substances fitting the dioxin profile into *either* category. As previously noted, the original proposal to upgrade dioxin stated, in the agency's own words, that the human studies showed only an "*association*" between dioxin and cancer. Am. Compl. Exh. 9 at RC-1. The agency thus admitted that the quantum of evidence on dioxin from studies in humans is "less than sufficient". That is what the word "association" means. The agency correctly observes (Opp. Br. at 37) that the reasonably anticipated criteria *also* allow listings where the evidence from studies in humans is "less than sufficient". If the agency is permitted to rely on mechanistic data to turn "less than sufficient" human evidence into "sufficient" human evidence, then any distinction between the two categories must evaporate.

Defendants gamely attempt to salvage a distinction between the categories by noting that the words "causal relationship between exposure ... and cancer" are present in the "known" criteria but are absent from the "reasonably anticipated". Opp. Br. at 37-38. This is circular reasoning, however, because any such ostensibly "causal relationship" would, under the agency's new reading, refer back to the mistakenly broadened term "studies in humans".

The agency maintains that, "clearly there is a difference in the *quantum* of evidence that must be marshaled to list a substance" and that the "known" category requires a "causal relationship". Opp. Br. at 37. Plaintiffs agree that, until the agency revealed its new position, the terms "sufficient" and "limited" had upheld this distinction. Now, however, the agency's position is that, for any given review, "limited" evidence from studies in humans might -- or might not -- be transmogrified into "sufficient" evidence through resort to the same mechanistic data that could also be used to support a "reasonably anticipated" listing. Plaintiffs agree that a basic difference between the categories, not only in the quantum of evidence but the kinds of evidence, should be preserved. Unfortunately, the agency has done away with this distinction.

D. The Agency Failed to Provide Notice and a Reasoned Explanation for Its Change In Position.

Critically, the agency is at a loss to point to a single statement -- before the present dispute arose -- in which (i) the *agency* announced, (ii) to the *public*, (iii) that it was making a *substantive* change, (iv) to the "*known*" criteria, and then (v) provided a *reasoned justification* for that change. Indeed, the record contains no such statement. Certainly none of the pre-decisional statements the agency has cited would constitute such an announcement, as they were neither official statements of the agency nor even statements in a public forum. Likewise, the two *Federal Register* "clarifications" of April 1999 do not contain such a statement.

E. The Agency Concedes that the Final Listing Decision Relies on

Essentially the Same Rationale as Stated in the Draft Background Document, Thus Making Clear Its Violation of the Listing Criteria.

In their Brief and in the district court Plaintiffs argued that the agency had apparently changed its rationale materially in the final listing addendum from that set out in the Draft Background Document ("DBD") (and Dr. Olden's recommendation, R. 32). Plaintiffs asserted that this maneuver negated the formal RoC review process by depriving the public, the RoC Subcommittee, and the NTP Executive Committee of the opportunity to review and comment on the rationale supporting the proposed listing decision. Recognizing the validity of this point, the agency now concedes that, although the wording of the rationale supporting the final listing decision was changed, there was actually no *substantive* change in the rationale from that set out in the DBD.[16] Thus, it is now clear that the final listing decision does rely on the three-part rationale set out in the DBD, which employs both experimental animal and *in vitro* evidence to compensate for less than sufficient evidence from studies "in humans" (i.e., epidemiologic evidence). Therefore it is clear that the listing is in plain violation of the "known" criteria.

CONCLUSION

[16]The agency nevertheless misapprehends Appellants' position on NTP's authority to change the DBD. The DBD is a "draft" only in the sense that the *listing* decision – i.e., whether to list or not – is not final until approved by the Secretary. However, the DBD *is* final in the sense that it reflects the final reasoning and evidence relied on by RG1 and RG2 and their recommendations. After completion by RG2, the DBD becomes, as stated by Dr. Lucier, the "document of record" and will be changed only to make technical corrections. Supp. S.J. Mem. Exh. 1 at 4.

For the foregoing reasons, and for the reasons set forth in Appellants' Brief, the September 30, 2000 order of the district court should be reversed, and the district court should be ordered to enter judgment for Plaintiffs.

Respectfully submitted,

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Dated: July 3, 2001

CERTIFICATE OF COMPLIANCE

I, Charles J. Fromm, counsel for Appellants, hereby certify that according to the word processing software utilized by my firm, the attached brief is 6,990 words in length and therefore complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) and D.C. Cir. Rule 32(a).

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Charles J. Fromm

Dated: July 3, 2001