United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 17, 2001 Decided November 23, 2001

No. 00-5364

Jim J. Tozzi in his personal capacity, and as President of Multinational Business Services, Inc., et al.,
Appellants

v.

U. S. Department of Health and Human Services, et al.,
Appellees

Appeal from the United States District Court
for the District of Columbia
(No. 99cv01170)

Charles J. Fromm argued the cause and filed the briefs for appellants.

Terry F. Quill was on the brief for amici curiae Public Health Scientists in support of appellants.

Peter D. Blumberg, Assistant U.S. Attorney, argued the cause for appellee. With him on the brief were Kenneth L. Wainstein, U.S. Attorney, and R. Craig Lawrence, Assistant U.S. Attorney.

Before: Tatel, Circuit Judge, Silberman and Williams*, Senior Circuit Judges.

Opinion for the Court filed by Circuit Judge Tatel.

Concurring opinion filed by Senior Circuit Judge Silberman.

Tatel, Circuit Judge: Acting pursuant to a provision of the Public Health Service Act that requires the Secretary of Health and Human Services to publish a list of substances "known" or "reasonably anticipated to be" human carcinogens, the Secretary upgraded the chemical dioxin from the "reasonably anticipated" to the "known" category. A manufacturer of products that release dioxin when incinerated, together with others allegedly affected by the upgrade, argue that the Secretary, in violation of HHS regulations, acted without sufficient epidemiological evidence that dioxin is a known human carcinogen. Although we reject the Secretary's arguments that the manufacturer lacks standing and that the upgrade decision is unreviewable, we agree with the district court that, given the deference owed an agency's interpretation of its own regulations, the Secretary acted neither arbitrarily nor capriciously.

I.

In 1978, Congress amended the Public Health Service Act to require the Secretary of Health, Education and Welfare, now Health and Human Services, to publish a list of known and suspected carcinogens. See Biomedical Research and Research Training Amendments, Pub. L. No. 95-622, Tit. II s 262, 92 Stat. 3412, 3435-36 (1978) (amending 42 U.S.C. s 241). Entitled the Report on Carcinogens, the list is

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* Senior Circuit Judge Williams was in regular active service at the time of oral argument.

prepared biennially by the Department's National Toxicology Program ("NTP"). Although HHS does not regulate substances based upon their inclusion in the Report, a listing--or in some instances an upgrade--may trigger obligations under other agency regulations. For example, OSHA's Hazard Communication Standard requires manufacturers to label as a carcinogen every substance listed in the Report. 29 C.F.R. s 1910.1200(d)(4)(i). See also id. s 1910.1450(e)(viii) (requiring OSHA-regulated laboratories to adopt special procedures for substances listed in the Report as known human carcinogens); 30 C.F.R. s 47.11 (defining some hazardous chemicals in part by reference to the Report and requiring Department of Labor-regulated mine operators to identify hazardous chemicals produced or brought on to mine property). A listing can also trigger obligations under state regulations. See Synthetic Organic Chem. Mfrs. Ass'n v. Sec'y, Dep't Health and Human Servs., 720 F. Supp. 1244, 1248 (W.D. Louisiana 1989) (listing triggered state regulatory provisions).

Before the Secretary may list (or delist) a substance, the substance undergoes a multi-step review process. See HHS Eighth Report on Carcinogens (1998), app. C. Acting on recommendations from the scientific community, the NTP begins by publishing in the Federal Register a list of substances that the agency believes merit consideration. At about the same time, an NTP committee, the Report on Carcinogens Review Committee, reviews the scientific literature and prepares a background document discussing the literature and recommending substances for listing. These recommendations, together with the background document and any public comments received in response to the Federal Register notice, are sent to two peer review committees: the NTP's Interagency Working Group (a committee composed of scientists from several federal agencies) and a subcommittee of the NTP's Board of Scientific Counselors (a chartered advisory committee). The subcommittee holds public hearings and receives written comments. Then, the subcommittee and the Working Group make formal recommendations to the NTP Executive Committee, which in turn makes a recommendation to the NTP Director. After independently evaluating the Executive Committee's recommendation, the Di-

rector submits a final draft of the Report to the Secretary. If the Secretary approves the Report, a notice is published in the Federal Register identifying all newly listed (or delisted) substances, classifying them as either "known" or "reasonably anticipated to be" human carcinogens, and announcing the availability of the latest Report. Of significance to this case, the Secretary may not move substances from one category to the other without going through the same formal review process. See Eighth Report (describing multi-step review process).

The Secretary has issued "criteria" for classifying substances as "known" or "reasonably anticipated to be" human carcinogens. As originally issued in 1982, the criteria provided:

Known to be Carcinogens:

> There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between the agent and human cancer.

Reasonably Anticipated to be a Human Carcinogen:

> A. There is limited evidence of carcinogenicity from studies in humans, which indicates that casual interpretation is credible, but that the alternative explanations, such as chance, bias or confounding, could not adequately be excluded, or
>
> B. There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant tumors: (a) in multiple species or strains, or (b) in multiple experiments (preferably with different routes of administration or using different dose levels), or (c) to an unusual degree with regard to incidence, site or type of tumor, or age at onset. Additional evidence may be provided by data concerning dose-response effects, as well as information on mutagenicity or chemical structure.

Eighth Report.

The parties agree that under these criteria only epidemiological studies were considered when placing a substance in the first category. Many in the scientific community, however, began to urge revision of the criteria to provide for broader consideration of "mechanistic" evidence--that is, evidence of the actual biochemical processes by which a substance causes cancer. In response, the Secretary published revised criteria in 1996. Because the differences between these criteria and the 1982 version are central to this case, we quote the new version in full:

Known to be a Human Carcinogen:

> There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between exposure to the agent, substance or mixture and human cancer.

Reasonably Anticipated to be a Human Carcinogen:

There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias or confounding, could not adequately be excluded; or

There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant and/or combined benign and malignant tumors: (a) in multiple species or at multiple tissue sites, or (b) by multiple routes of exposure, or (c) to an unusual degree with regard to incidence, site or type of tumor, or age at onset; or

There is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent belongs to a well defined structurally-related class of substances whose members are listed in a previous Annual or Biennial Report on Carcinogens as either known to be human carcinogen, or reasonably anticipated to be human carcinogen or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

> Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes but is not limited to dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Eighth Report.

The precise question before us is whether the final, unindented paragraph modifies both categories (as the Secretary interprets it) or only the "reasonably anticipated" category (as appellants claim).

This case involves the Secretary's decision to upgrade dioxin from the "reasonably anticipated" to the "known" category. A colorless, needle-shaped chemical not commercially produced, dioxin is released as a by-product of paper and pulp bleaching. See HHS Ninth Report on Carcinogens, Addendum (2001). Dioxin is also emitted during incineration of chlorine-containing materials, such as polyvinyl chloride ("PVC") plastic. Incineration of hospital waste, which usually contains PVC plastic, produces large quantities of dioxin. Id.

Chemically stable, dioxin persists in the environment for long periods of time. Because dioxin settles into soil and water, it ends up in animal fatty tissue and eventually meat and dairy products. According to the Ninth Report, human exposure occurs in several ways:

> Food is the major source (>90%) of human exposure to [dioxin] ... Other pathways of exposure include inhalation of [dioxin] from municipal, medical, and industrial waste incinerators and other incineration and combustion

> processes ... and ingestion of drinking water (0.01% of the daily intake).

Id. Most people have some level of dioxin in their tissues. Id.

The Secretary originally listed dioxin in the "reasonably anticipated" category. See Ninth Report supra. In 1997, however, the International Agency for Research on Cancer ("IARC"), a division of the World Health Organization that has its own carcinogen classification scheme, upgraded dioxin to its highest category based on "limited" epidemiological evidence and "strong" evidence that dioxin acts "through a relevant mechanism of carcinogenicity." Id. In response, the NTP proposed upgrading dioxin to the "known" category. After approval by the Report on Carcinogens Review Committee, the proposed listing was forwarded to the Working Group and the subcommittee of the Board of Scientific Counselors. The Working Group approved the upgrade, and after notice and public comment, so did the Board. The draft background document relied on both epidemiological and mechanistic evidence:

> [Dioxin] is known to be a human carcinogen based on several types of evidence:
>
> > Human studies have found an association between dioxin exposure and cancer mortality with respect to all cancers combined, non-Hodgkin's lymphoma, and lung cancer;
> >
> > Studies in experimental animals have shown that [dioxin] induces benign and malignant neoplasms at multiple issue [sic] sites in multiple species;
> >
> > A compelling body of evidence indicates a basic similarity in the mechanism of induction of animal and human tissue biochemical and toxicological responses to [dioxin] at comparable doses and tissue levels.

Draft RC Background Document (Sept. 30, 1997).

Following the Board's approval, Jim Tozzi, a "regulatory consultant" and an appellant in this case, sent a letter to the NTP Director stating that the Secretary may not list substances in the known category without "sufficient" evidence from epidemiological studies. Tozzi also complained that "[t]oo much was crammed into too little time" and that the NTP failed to provide certain "key" documents to the public. Responding to Tozzi's letter and conceding that "review had been inadequate," the NTP Director announced a "re-review" of dioxin "includ[ing] another open, public review by the NTP Board Subcommittee." At the same time, the Director emphasized his belief that "the criteria [had been] appropriately applied." After the additional round of notice and comment, the Board of Scientific Counselors voted against the upgrade, but both the NTP Executive Committee and the NTP Director approved it. Concurring with the Director, the Secretary listed dioxin in the Ninth Report as a known carcinogen.

Tozzi, together with Brevet Industries, a manufacturer of disposable plastic connectors used during open heart surgery, the Empire State Restaurant & Tavern Association, and Greenbaum & Gilhooleys, a New York restaurant, then filed suit in the United States District Court for the District of Columbia pursuant to the Administrative Procedure Act, 5 U.S.C. 702-706, claiming that the Secretary acted arbitrarily and capriciously by upgrading dioxin without sufficient epidemiological evidence that it causes cancer in humans. Finding the Secretary's interpretation of the criteria "eminently reasonable," the district court granted summary judgment for the Department. See Tozzi v. United States Dep't of Health and Human Servs., No. 99-1170 (D.D.C. Sept. 30, 2000). Tozzi, Brevet, and the culinary plaintiffs now appeal. Our review is de novo. Russell v. Principi, 257 F.3d 815, 818 (D.C. Cir. 2001)

II.

We begin with two threshold issues. The Department argues that none of the appellants has standing to challenge the dioxin upgrade and that, in any case, listing decisions are unreviewable. We consider each argument in turn.

Standing

To have Article III standing, a plaintiff must demonstrate an "actual or immediate" "injury-in-fact" that is "fairly traceable" to the challenged conduct and "likely" to be "redressed by a favorable decision." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (internal quotations marks omitted). The plaintiff's allegations must not be purely "speculative--the ultimate label for injuries too implausible to support standing." Advanced Mgmt. Tech., Inc. v. FAA, 211 F.3d 633, 637 (D.C. Cir. 2000) (internal quotation marks omitted). Applying this standard, the district court found that Brevet had standing.

The Department first argues that Brevet has failed to show actual or immediate injury. We disagree. According to an affidavit submitted by Brevet's president, over ninety-five percent of the company's sales depend on the continued use of PVC plastic by the medical establishment. Brewer Aff. p 10. The president also states that healthcare companies, pressured by environmental groups, have expressed concern over the dioxin hazards associated with incineration of PVC medical supplies; that some municipalities have adopted resolutions calling for the phasing out of all, or nearly all, PVC-containing products, including medical supplies; and that Brevet's "profits, reputation and goodwill" would be adversely affected if an "authoritative U.S. government agency issue[d] and widely disseminate[d] a report implying ... that Brevet's products are responsible for introducing a known human carcinogen into the environment." Id. p p 6-9.

Record evidence supports Brevet's claims. Three California municipalities--San Francisco, Oakland and Berkeley--adopted resolutions forcefully calling for healthcare institutions to eliminate their use of PVC plastic. See City and County of San Francisco Resolution No. 021-98-COE (Sept. 8, 1998); Oakland City Council Resolution No. 74778 (Feb. 2, 1999); Berkeley Resolution No. 60, 196-N.S. (Sept. 14, 1999). Elsewhere, state and local agencies from Hartford, Connecticut, to Charlotte, North Carolina, to Seattle, Washington, have held hearings on PVC plastic use. See Center for

Health, Environment and Justice, Dioxin Public Event Update (Nov. 4, 1999). Supporting Brevet's claim that environmental groups are pressuring healthcare providers to reduce or eliminate the use of PVC plastic, record evidence demonstrates that Tenet Healthcare Corporation, which annually purchases over three billion dollars worth of medical supplies, has announced that it will seek to purchase PVC-free products. See Press Release, Healthcare Without Harm, Tenet Prefers Non-PVC Medical Products (Oct. 6, 1999) Other Brevet customers (actual and potential) including Baxter International, Universal Health Services, Kaiser Permanente and Catholic Healthcare West have announced similar moves. Id. We thus think it not at all "speculative," Advanced Mgmt., 211 F.3d at 637, to expect that Brevet, a company whose revenues depend almost entirely on the continued use of PVC plastic in the medical industry, will experience reduced profits. See DIRECTV, Inc. v. FCC, 110 F.3d 816, 829 (D.C. Cir. 1997) ("[S]tanding ... may be established by reference ... to lost profits....").

The Department next argues that even if Brevet's profits were to decline, that injury would not be "fairly traceable" to the dioxin upgrade. Lujan, 504 U.S. at 590 (internal quotation marks omitted). The Department points out that the anti-dioxin movement predates the listing process. It also claims that pressure on government agencies to regulate dioxin and on healthcare companies to reduce the use of PVC products will continue whether or not dioxin remains listed as a known human carcinogen.

Even if the Department's claims were true, we disagree that Brevet has failed to show that its injury is fairly traceable to the dioxin upgrade. As we pointed out in Block v. Meese, we have never applied a "tort" standard of causation to the question of traceability. 793 F.2d 1303, 1309 (D.C. Cir. 1986). Where, as here, the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties, we have required only a showing that "the agency action is at least a substantial factor motivating the third parties' actions." Cmty. for Creative Non-violence v. Pierce, 814 F.2d 663, 669 (D.C. Cir. 1987). For

example, we have allowed plaintiffs claiming that regulatory changes have caused "competitive injury," defined only as "exposure to competition," to sue the regulating agencies, even though the harm resulted most directly from independent purchasing decisions of third parties. Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1499 (D.C. Cir. 1996); Liquid Carbonic Indus. Corp. v. FERC, 29 F.3d 697, 701 (D.C. Cir. 1994) (citing cases).

Applying this standard to the facts of this case, we have little doubt that the dioxin upgrade will represent a "substantial factor" in the decisions of state and local agencies to regulate products containing dioxin or of healthcare companies to reduce or end purchases of PVC plastics. Congress intended the Report on Carcinogens to serve as the federal government's authoritative statement on the current state of knowledge regarding the carcinogenicity of various chemicals. See H. R. Rep. No. 95-1192, at 28 (1978) (referring to the list as a "comprehensive document" containing "all known or suspected carcinogenic agents"). Congress also intended the list to serve as a resource for state, federal and local regulatory authorities. See id. (requiring that the list include "an evaluation of the efficacy of appropriate existing regulatory standards, and recommendations regarding the need to improve these standards"). These hopes regarding the list's importance have been realized. The list is widely disseminated and highly influential: A member of the Board of Scientific Counselors noted that "the Report on Carcinogens ... is a very important document.... It is used ... by a number of regulatory groups both nationally as well as internationally and I think it has a very large impact on preventing possible hazards to the U.S. public...." Tr. Proceedings, Board of Scientific Counselors, Report on Carcinogens Subcommittee Meeting at 10 (Oct. 30, 1997). Thus, contrary to the Department's argument, we think it not at all "speculative" to expect that the dioxin upgrade will cause some non-trivial number of state and local agencies to regulate dioxin. Indeed, the Berkeley, Oakland, and San Francisco resolutions all cite the initial Review Committee's preliminary determination for the proposition that dioxin is "known" to be a human carcinogen,

not merely hypothesized to be carcinogenic. See Resolutions, supra at 9. Because of the Report's importance, moreover, we have no doubt that the Secretary's decision to upgrade dioxin will cause some non-trivial number of healthcare companies, already under pressure from environmental activists, to reduce or end their use of PVC plastics.

An additional factor reinforces our conclusions regarding both injury and causation: When the government attaches an inherently pejorative and damaging term such as "carcinogen" to a product, the probability of economic harm increases exponentially. The Department's reliance on Block, in which the government's label of "propaganda" was not inherently pejorative, is therefore misplaced. It is not too speculative to conclude that the Report will injure Brevet economically, even with the presence of other causal factors. See, e.g., Mountain States Legal Found. v. Glickman, 92 F.3d 1228, 1234-35 (D.C. Cir. 1996) (holding incremental risk of forest fires from Forest Service's challenged decision sufficient to support Article III standing, despite existence of other causal factors for forest fires).

Equally without merit is the Department's contention that even assuming a likely injury fairly traceable to the dioxin upgrade, Brevet's injury is not "redressable." Lujan, 504 U.S. at 561. While it may be true, as the Department insists, that municipalities and healthcare providers will not reverse decisions to limit PVC use, we do not agree that "Brevet's alleged future harm could not be redressed by a decision of this Court." Appellee's Br. at 19. Nothing in the record indicates that any other federal agency has labeled dioxin a "known" carcinogen and, asked about this at oral argument, counsel for the Department was unable to name one either. Thus, were we to set aside the Secretary's upgrade decision, dioxin activists could no longer point to an authoritative determination by the United States government that dioxin is "known" to cause cancer in humans. Conversely, Brevet could point out that a government report widely accepted as comprehensive no longer lists dioxin as a "known" carcinogen. State and local governments would be less likely to regulate

dioxin, and healthcare companies would in turn be less likely to stop using PVC plastic. In short, reclassifying dioxin would redress at least some of Brevet's economic injury.

Because Brevet has Article III standing, we need not consider whether the culinary appellants and Tozzi have standing as well. See Watt v. Energy Action Educ. Found., 454 U.S. 151, 160 (1981) (declining to address standing of remaining plaintiffs after finding one plaintiff with standing); Mountain States, 92 F.3d at 1232 (same).

Reviewability

Reviewability under the APA hinges upon whether the listing has "legal effect, which in turn is a function of the agency's intention to bind either itself or regulated parties." Kennecott Utah Copper Corp. v. United States Dep't of Interior, 88 F.3d 1191, 1223 (D.C. Cir. 1996). In making this determination, we have sometimes looked to "the agency's own characterization of its action" and to "publication or the lack thereof in the Federal Register or the Code of Federal Regulations." Am. Portland Cement Alliance v. EPA, 101 F.3d 772, 776 (D.C. Cir. 1996). Where the agency characterizes its action as non-binding or does not publish in the Federal Register, we have found the action unreviewable. See, e.g., id. (finding agency's "regulatory determinations" unreviewable because not published and not characterized as binding); Telecomms. Research & Action Ctr. v. FCC, 800 F.2d 1181, 1186 (D.C. Cir. 1986) (finding document to be merely general policy statement in part because agency characterized it as produced "solely for the purpose of reference and convenience") (internal quotation marks and citation omitted).

Seizing upon these two indicia of unreviewability, the Department argues that the listing is unreviewable. It points out that the Report's preamble states that it is "for informational purposes only" and that the Secretary never published the entire report in the Federal Register. Taken alone, the characterization of the Report as informational might well support a conclusion that the Report has no "legal effect."

Kennecott Utah Copper, 88 F.3d at 1223. Additional considerations, however, lead us to conclude otherwise.

To begin with, although the final Report was not published in the Federal Register, the Secretary did publish a notice proposing a dioxin upgrade and, once finalized, a summary of the decision. Equally important, even though the Secretary takes no action pursuant to a listing, the contention that a listing has no "binding effect," Appellee's Br. at 25, is inaccurate: Listing a substance as a human carcinogen triggers obligations under OSHA, Department of Labor and state regulations. See supra at 3. Additional evidence of a listing's "legal effect" comes from the fact that in order to remove a substance from either category, the Secretary must undertake the same elaborate procedure--including notice and comment--required for an initial listing. See supra at 3-4.

Nothing in Industrial Safety Equipment Association v. EPA, 837 F.2d 1115 (D.C. Cir. 1988), requires a different result. In that case, we found unreviewable an agency guide that ranked respirators, emphasizing that the guide repeatedly noted that it was not discussing a "regimen presently mandated by law." Id. at 1120. By contrast, the carcinogen classification scheme is mandated by the Public Health Act. See 42 U.S.C. s 241(b)(4)(A). Moreover, the respirator guide was never published in the Federal Register, nor did inclusion of respirators in the guide trigger other regulatory obligations. Indus. Safety, 837 F.2d at 1121.

Having found that Brevet has standing and that the listing is reviewable, we turn to the merits.

III.

Brevet argues that by upgrading dioxin on the basis of mechanistic rather than epidemiological evidence, the Secretary acted arbitrarily and capriciously. See 5 U.S.C. s 706(2)(A). According to Brevet, the criteria's final paragraph, which permits the use of mechanistic evidence, applies only to the "reasonably anticipated" category, leaving unaffected the traditional understanding that the Secretary may

list a substance in the "known" category only if there is "sufficient" evidence from epidemiological studies. Interpreting the criteria differently, the Department insists that the last paragraph applies to both categories, thus permitting reliance on mechanistic evidence when classifying substances as known carcinogens. In support of this interpretation, the Department points out that the version appearing in the published Report, quoted in full earlier in this opinion, supra at 5-6, shows the last paragraph with wider margins than the preceding paragraphs.

Because Brevet challenges the Secretary's interpretation of an HHS regulation (Brevet nowhere argues that the criteria are not a regulation), we owe the Secretary "substantial deference." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994). We "need not find that the agency's construction is the only possible one, or even the one that the court would have adopted in the first instance." Wyo. Outdoor Council v. United States Forest Serv., 165 F.3d 43, 52 (D.C. Cir. 1999). Indeed, we give the agency's interpretation "controlling weight," Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945), unless an "alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation." Consolidation Coal Co. v. Fed. Mine Safety and Health Review Comm'n, 136 F.3d 819, 822 (D.C. Cir. 1998) (internal quotation marks and citation omitted). Brevet falls far short of meeting this highly deferential standard.

For one thing, not only does the absence of indentation support the Secretary's interpretation, but Brevet points to no textual evidence demonstrating that the last paragraph applies only to the "reasonably anticipated" category. Brevet argues that the Secretary's interpretation completely defeats language in the "known" category, which the company says requires "studies in humans" (meaning, according to Brevet, exclusively epidemiology) that are "sufficient" to "indicate[ ] a causal relationship" between the substance and cancer. Thus, Brevet says, a substance that fails that test cannot be classified as such. At most, however, Brevet has shown an

inconsistency between the criteria's formatting (the absence of indentation) and the "known" category's text, in which case we would defer to the Secretary's resolution of the contradiction. See Cold Spring Granite Co. v. Fed. Mine Safety and Health Review Comm'n, 98 F.3d 1376, 1378 (D.C. Cir. 1996) ("The Secretary's plausible and sensible reading of his own regulation would prevail even if the company had presented an equally plausible alternative construction.").

Brevet next argues that "contemporaneous evidence" indicates that the Secretary had no intention of broadening the "known" criteria through the 1996 revisions. Appellants' Opening Br. at 23-27. In support of this argument, Brevet points to a press release issued by the Secretary's Office on the day the revised criteria were published and to an article in Environmental Health Perspectives, the NTP's official newsletter, both of which state that the criteria for listing in the "known" category remain "unchanged." We see nothing in either document demonstrating that the interpretation the Department offers here "marks a departure from [the Secretary's] stated prior understanding in enacting the regulation." Consolidation Coal, 136 F.3d at 822. Although portions of the press release quote the Secretary, the statement that the criteria for the "known" category remain unchanged was not a quotation, nor does anything in the record indicate that the Secretary or any official with authority to interpret the criteria authorized the statement. In addition to suffering from the same defect, the newsletter is at best ambiguous. Although saying that the 1996 criteria for the "known" category are substantively unchanged, the newsletter, after quoting the criteria's final paragraph in full, states that "the last factor is especially important 'for the reasonably anticipated to be a human carcinogen category' " [emphasis added]. The phrase "especially important" suggests that the final paragraph applies to the "known" category as well.

The decision of the district court is affirmed.

So ordered.

Silberman, Senior Circuit Judge, concurring: I concur with all parts of the court's opinion including the portion dealing with reviewability. But it is an interesting question how one should categorize the agency's action that we review. It might be thought to be an informal adjudication--a specific application of the regulation--but because it has only a future effect, I think it is accurately described as an interpretive rule. It certainly has more bite than the typical policy statement, many of which are not reviewable at all. See, e.g., Kennecott Utah Copper v. United States Dep't of Interior, 88 F.3d 1191, 1223 (D.C. Cir. 1996). In that regard, I should like to express a view on the question raised by the panel in Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021-22 (D.C. Cir. 2000). In that case the panel, recognizing our split of authority, suggested that virtually all agency statements of future effect--including policy statements--were rules under the broad definitional language of s 551(4).

> "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganization thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing; ....

The panel said "virtually all," but in light of its suggested disagreement with Syncor International Corp. v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997), which described a typical policy statement as only an indication of an agency's enforcement policy, I cannot imagine what the panel meant to exclude-or given its reasoning what could be excluded.

The panel criticized Syncor and our prior opinions on which Syncor relied for not considering explicitly the APA definition, but no less an administrative law authority than Justice Scalia once wrote:

> Since every statement is of either general or particular applicability, and since everything an agency does is "designed to implement, interpret, or prescribe law or policy, etc." the only limiting (that is to say, defining) part of the definition is "agency statement of ... future effect." This is of course absurd. ... [Therefore] it is generally acknowledged that the only responsible judicial attitude toward this central APA definition is one of benign disregard.

Scalia, Vermont Yankee: The APA, the D.C. Circuit, and the Supreme Court, 1978 Sup. Ct. Rev. 345, 383.

I agree with then-Professor Scalia that the panel's interpretation is not a reasonable reading ("absurd" might be too strong). Not every utterance, not every speech (with only future effect) legitimately can be described as a rule. Perhaps the key to the definition is the word "prescribed," which in Random House College Dictionary, means "to lay down a rule" (emphasis added), and in the 1941 Webster's New International Dictionary meant "to lay down authoritatively as a guide" (emphasis added). In other words, Congress surely meant that an agency statement that serves the purpose of a rule is a rule. If it walks like a rule, and quacks like a rule--i.e., is laid down--it is a rule. But any agency statement which does not seek to authoritatively answer an underlying policy or legal issue does not fit that criteria. In this case, the agency authoritatively proclaims which substances qualify as known carcinogens, which is why I think it is properly described as an interpretive rule.