United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Filed April 2, 1999

No. 98-5043

DURK PEARSON AND SANDY SHAW,
AMERICAN PREVENTIVE MEDICAL ASSOCIATION AND
CITIZENS FOR HEALTH,
APPELLANTS

v.

DONNA E. SHALALA, SECRETARY,

UNITED STATES DEPARTMENT OF HEALTH AND

HUMAN SERVICES, ET AL.,

APPELLEES

Consolidated with
98-5084

On Appellees' Suggestion for Rehearing En Banc

Before: EDWARDS, Chief Judge, WALD, SILBERMAN, WILLIAMS,

GINSBURG, SENTELLE, HENDERSON, RANDOLPH, ROGERS, TATEL, and

GARLAND, Circuit Judges.

O R D E R

Upon consideration of appellees' suggestion for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the suggestion be denied.

Per Curiam
FOR THE COURT:

Mark J. Langer, Clerk

BY: Robert A. Bonner
Deputy Clerk

A statement by Circuit Judge SILBERMAN is attached.

SILBERMAN, *Circuit Judge*, concurring in the denial of rehearing en banc: The government, in its petition for rehearing and suggestion for rehearing en banc, advances an argument that it did not present at any stage in this appeal--the government candidly concedes as much. We are told that the panel's decision is anomalous in light of the regime that governed the sale and labeling of dietary supplements prior to Congress' enactment of the Nutrition Labeling and Education Act of 1990, 104 Stat. 2353. This Act created a safe harbor from drug status (and the rigorous testing attendant thereto) for certain dietary supplements whose labels include health claims. Under the prior regime, putting a health claim on a dietary supplement transformed the dietary supplement into a "drug," thereby triggering the rigorous drug approval process. The government asserts that neither employing a health claim as a trigger to the drug approval process (which was never tested in litigation), nor subjecting "drugs" to the drug approval process, raises a First Amendment concern. From this premise, the government now reasons that the FDA's present approach of exempting from drug status only those health-claim bearing dietary supplements whose claims attain "significant scientific agreement" easily passes muster because the greater power to subject a health-claim bearing dietary supplement to the drug approval process must include the lesser to refuse to exempt some health claim-bearing dietary supplements from the drug approval process. (The government also seems to suggest that the statutory provisions governing the labeling of drugs, which applied to *all* health claim-bearing dietary supplements prior to 1990, survive First Amendment scrutiny, and hence that today's statutory and regulatory provisions governing the labeling of dietary supplements should be upheld.)

While I am dubious of the force of such "greater includes the lesser" logic in the commercial speech context, see *44 Liquormart, Inc. v. Rhode Island*, 584 U.S. 484, 510-13 (1996) (plurality), I do not think it appropriate for us to formally consider and to decide this argument. The government, like any other litigant, cannot be heard to advance a major non-jurisdictional argument for the first time at the rehearing stage. That would be palpably unfair to appellants and would jeopardize our own ability to process cases efficiently. *See*, e.g., *Benavides v.* DEA, 976 F.2d 751, 753 (D.C. Cir. 1992); *Keating v.* FERC, 927 F.2d 616, 625 (D.C. Cir. 1991); *Schooler v. Schooler*, 173 F.2d 299, 303 (D.C. Cir. 1949). Indeed, we even refuse to consider arguments an appellant asserts for the first time in a reply brief. *See, e.g., Adams v. Hinchman*0, 154 F.3d 420, 424 n.7 (D.C. Cir. 1998).

Apart from this argument, the government has misrepresented the panel's opinion in several respects, two of which deserve brief mention. The government claims that the panel ""mistakenly believed that FDA has no concern that the use of dietary supplements may threaten consumer health and safety." To the contrary, we stated that "[i]t is important to recognize that the government does not assert that appellants' dietary supplements in any fashion threaten [a] consumer's health and safety." *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (footnote omitted) (first emphasis added). The government has never contended that *appelants'* dietary supplements, as opposed to other dietary supplements not at issue in this litigation, threaten consumers' health and safety.

Second, the government describes the panel as "concluding that it was arbitrary under the APA for FDA not to specify in advance precisely what evidence will establish 'significant scientific agreement.'" This seems a careless interpretation of the opinion. We took care to acknowledge that although "the APA requires the agency" [to] giv[e] some definitional content to the phrase 'significant scientific agreement,'" *Pearson*, 164 F.3d 660, "[t]hat is not to say that the agency was necessarily required to define the term in its initial general regulation--or indeed that it is obliged to issue a comprehensive definition all at once," *id*. at 661. To be sure, we also observed in *dicta* that the First or Fifth Amendments might, in some respects, bear on the agency's discretion. *See id*. at 660 n.12. But the opinion is quite clear that case-by-case development of the "Significant scientific agreement" standard is consistent with the APA.