UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 05-1937

DURK PEARSON; SANDY SHAW,

Plaintiffs - Appellants,

versus

MICHAEL LEAVITT, in his official capacity as Secretary of the U.S. Department of Health and Human Services; LESTER M. CRAWFORD, in his official capacity as Acting Commissioner of the U.S. Food and Drug Administration; UNITED STATES FOOD AND DRUG ADMINISTRATION; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; UNITED STATES OF AMERICA,

Defendants - Appellees.

Appeal from the United States District Court for the District of Maryland, at Greenbelt. Alexander Williams, Jr., District Judge. (CA-04-3600-AW)

Argued: May 22, 2006 Decided: June 23, 2006

Before WILKINSON and TRAXLER, Circuit Judges, and Richard L. WILLIAMS, Senior United States District Judge for the Eastern District of Virginia, sitting by designation.

Affirmed by unpublished per curiam opinion.

ARGUED: Jonathan Walker Emord, EMORD & ASSOCIATES, P.C., Reston, Virginia, for Appellants. Matthew Miles Collette, UNITED STATES DEPARTMENT OF JUSTICE, Civil Division, Appellate Section, Washington, D.C., for Appellees. **ON BRIEF:** Michelle C. Gayeski,

EMORD & ASSOCIATES, P.C., Reston, Virginia, for Appellants. Peter D. Keisler, Assistant Attorney General, Rod J. Rosenstein, United States Attorney, Douglas N. Letter, UNITED STATES DEPARTMENT OF JUSTICE, Civil Division, Appellate Section, Washington, D.C., for Appellees.

PER CURIAM:

Durk Pearson and Sandy Shaw ("Appellants") sought and were denied declaratory and injunctive relief to preclude the Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS")(collectively "Appellees") from taking action to prevent Appellants from selling a report published by the United States government that suggests that dietary supplements containing S-adenosyl-L-methionine("SAMe") were a possible treatment for various diseases. Appellants claimed that the potential for FDA enforcement of its regulations chilled their constitutionally protected First Amendment free speech rights. Finding that there is not a sufficient factual basis upon which to make a determination of Appellants' claims, we agree with the district court's ruling that the controversy is not ripe and accordingly affirm the dismissal of the claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

I.

Durk Pearson and Sandy Shaw are formulators of dietary supplements containing SAMe. Appellants receive royalties from distributors who are licensed to sell their products. SAMe is an amino acid created within human cells by the energy molecule ATP and the amino acid methionine. SAMe plays a role in many of the biochemical reactions in the human body. SAMe has been the subject

of research by privately funded organizations and by federal government agencies.

In October 2002, the Agency for Healthcare Research and Quality ("AHRQ"), a division of HHS, published a report entitled "S-Adenosyl-L-Methionine for the Treatment of Depression, Osteoarthritis, and Liver Disease"(the "Report"). The Report summarized the conclusions of various published studies examining the effect of SAMe on the treatment of depression, osteoarthritis, and liver disease. The Report concluded that supplements containing SAMe are more effective than placebos in the treatment of depression and osteoarthritis but were no more effective in treating liver disease. The Report was made available to the public on at least seven different websites.

In 2004, Appellants wrote a prologue to the Report, touting its findings and explaining the role of SAMe in bodily processes. Appellants intended to sell a bound volume consisting of their prologue and the Report (collectively the "Publication") to the general public through their licensees.

Appellants refrained from selling the Publication because of fear of prosecution by the FDA. Specifically, Appellants feared that the FDA, under their administrative enforcement policy, would use the Publication as evidence of the "intended use" of the dietary supplements and reclassify Appellants' SAMe-containing dietary supplements as "new drugs" under the Food Drug and

Cosmetics Act ("FDCA"), thus prohibiting sale of the Publication to consumers.

In November 2004, Appellants brought this action seeking a declaration that the potential enforcement of FDA regulations was a violation of their First Amendment right to free speech. Appellants also sought to enjoin Appellees from declaring the Publication as evidence of an intent to sell the SAMe-containing dietary supplements as "new drugs" and from taking any action to prohibit Appellants' licensees from selling the Publication to the public. At the time the action was filed, the FDA had not threatened or implemented any procedures to either prohibit the sale of the Publication or to prosecute Appellants for FDA violations.

Appellants moved for summary judgment and Appellees moved to dismiss or, in the alternative, for summary judgment. The district court ruled that there was not a sufficient factual record upon which to make a determination regarding the validity of Appellants' claims and that the case was not ripe, and granted Appellees' motion to dismiss. This appeal followed.

II.

Ripeness requirements are relaxed in First Amendment cases because of the potential chilling effect of unconstitutional restrictions on free speech. Forsyth County v. Nationalist

Movement, 505 U.S. 123, 129-30 (1992). To withstand a ripeness challenge, a plaintiff must demonstrate "a live dispute involving the actual or threatened application of [a statute or policy] to bar particular speech." Renne v. Geary, 501 U.S. 312, 320 (1991). But without a factual record of an actual or threatened action resulting in the suppression of free speech, no ripe, justiciable controversy exists. Woodall v. Reno, 47 F.3d 656, 656 (4th Cir. 1995); see Jordahl v. Democratic Party of Virginia, 122 F.3d 192, 198 (4th Cir. 1997).

In evaluating the ripeness of a claim for judicial review, courts must consider (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration. Abbott Labs v. Gardner, 387 U.S. 136, 149 (1967); overruled on other grounds by Califano v. Sanders, 430 U.S. 99 (1977). Regarding administrative agency cases, this court has held that a claim is not ripe for review unless the issues to be considered are purely legal ones and the agency rule giving rise to the claim is final and not dependent on future uncertainties or intervening agency rulings. Charter Fed. Sav. Bank v. Office of Thrift Supervision, 976 F.2d 203, 208 (4th Cir. 1992). If certain critical facts that would substantially assist the court in making its determination are contingent or unknown, the case is not ripe for judicial review. Arch Mineral Corp. v. Babbitt, 104 F.3d 660, 665-66 (4th Cir. 1997).

Appellants have offered insufficient evidence to demonstrate the fitness for judicial review that ripeness requires. Appellants claim that the FDA will use their Publication as evidence of the "intended use" of their SAMe containing supplements. However, the record is devoid of any evidence that would support this contention. There is no indication of who will sell the Publication, how the Publication will be marketed, the purpose for which the Publication will be used, or the way in which it will be distributed. These factors are a necessary part of the analysis of the "intended use" of a product. In United States v. An Article of Drug Consisting of 250 Jars etc. of U.S. Fancy Pure Honey, etc., 218 F. Supp. 208, 209-11(E.D. Mich. 1963), aff'd, 344 F.2d 288 (6th Cir. 1965), the court found that jars of honey were unapproved drugs because booklets containing statements about the honey's disease-treating capacity were sold adjacent to the jars of honey. In United States v. 24 Bottles 'Sterling Vinegar & Honey, etc.'(Balanced Foods Inc.), 338 F.2d 157(2d Cir. 1964), the Second Circuit held that booklets claiming the curative power of honey were not evidence of intended use because they were shelved with other publications and were not marketed with the honey in any way. Accordingly, any determination of "intended use" must be grounded in a fact-based inquiry and cannot be based on speculative contentions. Appellees have neither threatened nor taken action against Appellants. There has been no final agency determination

of the Publication as evidence of intended use. Because Appellants have not shown such action on the part of Appellees, there is no issue to decide and judgment must be deferred.

In a ripeness inquiry, hardship is determined by considering (1) the immediacy of the threat and (2) the burden imposed upon the party compelled to act under threat of enforcement of the challenged law. Charter, 976 F.2d at 208-09. The threatened harm must be "immediate, direct, and significant." West Virginia Highlands Conservancy, Inc. v. Babbit, 161 F.3d 797, 800 (4th Cir. 1998)(citations omitted). Appellants' complaint meets none of these requirements. Appellants allege harms relating to the loss of free speech, the right to sell the Publication via their licensees, and the loss of royalties from sales of the Publication and their SAMe dietary supplements. These alleged losses are not immediate, Appellants have not undertaken any campaign to sell the Publication, and the FDA has not made a final determination regarding the Publication as evidence of the "intended use" of Appellants' product. These issues prevent the court from making a determination as to whether an immediate threat exists that requires the injunction that Appellants seek. Any losses or hardship suffered by Appellants would be contingent on these factual circumstances.

For the foregoing reasons, we conclude that the instant matter is not ripe for disposition and the district court's decision is AFFIRMED.