

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION**

FARM-TO-CONSUMER LEGAL
DEFENSE FUND, LAURIE
DONNELLY, JENNIFER ALLEN, DR.
JOSEPH HECKMAN, DANE MILLER,
CYNTHIA LEE ROSE, ERIC
WAGONER, ANNE COOPER, and
MICHAEL BUCK,

Plaintiffs,

vs.

KATHLEEN SEBELIUS, in her official
capacity as Secretary, United States
Department of Health and Human
Services, UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES, MARGARET
HAMBURG, in her official capacity as
Commissioner, United States Food and
Drug Administration, and UNITED
STATES FOOD AND DRUG
ADMINISTRATION,

Defendants.

No. C 10-4018-MWB

**MEMORANDUM OPINION AND
ORDER REGARDING
DEFENDANTS' RENEWED MOTION
TO DISMISS AND, IN THE
ALTERNATIVE, MOTION FOR
SUMMARY JUDGMENT AND
PLAINTIFFS' MOTION FOR
SUMMARY JUDGMENT**

In this case, the plaintiffs challenge the validity of Food and Drug Administration (FDA) regulations requiring “milk” in final package form for beverage use to be pasteurized or ultrapasteurized, *see* 21 C.F.R. § 131.110, and prohibiting the delivery into interstate commerce of any milk in final package form for direct human consumption

unless the product has been pasteurized. *See* 21 C.F.R. § 1250.61. This case is before me on the defendants' May 11, 2011, Renewed Motion To Dismiss And, In The Alternative, Motion For Summary Judgment (docket no. 50), and the plaintiffs' June 10, 2011, Motion For Summary Judgment (docket no. 57). I denied that part of the defendants' first Motion To Dismiss (docket no. 10), filed April 26, 2010, asserting lack of subject matter jurisdiction, on standing and ripeness grounds, without prejudice to a full factual challenge. I now find that the dispositive question is whether the plaintiffs have standing to pursue their challenges to the validity of the regulations.

“To satisfy Article III’s standing requirement, (1) there must be ‘injury in fact’ or the threat of ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury must be fairly traceable to defendant’s challenged action; and (3) it must be likely (as opposed to merely speculative) that a favorable judicial decision will prevent or redress the injury.” *Gray v. City of Valley Park, Mo.*, 567 F.3d 976, 984 (8th Cir. 2009). It is now clear that the plaintiffs have no “injury in fact” and no “actual or imminent” “threat of injury in fact,” but only a “conjectural or hypothetical” threat of injury. *Id.*

As to “injury in fact,” with the exception of plaintiff Wagoner, the plaintiffs have not even alleged that the FDA has applied or sought to apply the challenged regulations to them, and Wagoner’s contentions are merely conclusory and based on speculation. Although Wagoner admits in his affidavit that a Georgia Department of Agriculture (GDA) official, by telephone, ordered an embargo of raw milk that he had transported from South Carolina, where it is legal to buy raw milk, to Georgia, where it is not, he nevertheless contends that the embargo was ordered at the direction of the FDA and that the GDA agents identified federal rules as the basis for the embargo. *See* Plaintiffs’ Appendix at 35 (Wagoner’s Affidavit at ¶ 22). There is no dispute that no FDA agent was present at the

farmers market where Wagoner's raw milk was discovered, and no indication from the record that any FDA agent was contacted prior to GDA officials ordering the embargo on the raw milk or their statements that the embargoed raw milk would have to be destroyed.

Here, Wagoner's allegations that the FDA, rather than the GDA, enforced the embargo and destruction of his raw milk do not generate reasonable inferences, because they are conclusory and speculative. *See Wierman v. Casey's Gen. Stores*, 638 F.3d 984, 993 (8th Cir. 2011) (citing *Hitt v. Harsco Corp.*, 356 F.3d 920, 923-24 (8th Cir. 2004)); *Elam v. Regions Fin. Corp.*, 601 F.3d 873, 877 (8th Cir. 2010) (noting that, on summary judgment, while the evidence and reasonable inferences drawn from it must be viewed in the light most favorable to the non-moving party, "these inferences must be 'reasonable inferences—those that can be drawn from the evidence without resort to speculation'" (quoting *P.H. v. School Dist. of Kansas City*, 265 F.3d 653, 658 (8th Cir. 2001), in turn quoting *Sprenger v. Federal Home Loan Bank of Des Moines*, 253 F.3d 1106, 1110 (8th Cir. 2001)); *Rose-Maston v. NME Hospitals, Inc.*, 133 F.3d 1104, 1109 (8th Cir. 1998) (conclusory affidavits, standing alone, cannot create genuine issues of material fact precluding summary judgment). Thus, his is a "[a] case founded on speculation or suspicion," and as such, "is insufficient to survive a motion for summary judgment." *Yarborough v. DeVilbiss Air Power, Inc.*, 321 F.3d 728, 730 (8th Cir. 2003) (quoting *National Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602, 610 (8th Cir. 1999)).

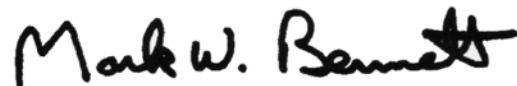
Moreover, the record is now clear that there is no "threat of injury in fact," *Gray*, 567 F.3d at 984, to establish standing for any of the plaintiffs, where the FDA has made abundantly clear that it has not and does not intend to enforce the regulations against any of the plaintiffs. *See Defendants' Status Report Of March 16, 2011* (docket no. 43), Exhibit A, 8-10 (internal pages 7-9) (FDA's response to the court's questions *ante*); Plaintiffs' Appendix (as amended) at 292 (FDA's press release, dated November 1, 2011,

stating, *inter alia*, “With respect to the *interstate* sale and distribution of raw milk, the FDA has never taken, nor does it intend to take, enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption.” (emphasis in the original)).

THEREFORE, the defendants’ May 11, 2011, Renewed Motion To Dismiss And, In The Alternative, Motion For Summary Judgment (docket no. 50) is **granted**, to the extent that this matter is **dismissed** for lack of subject matter jurisdiction, owing to lack of standing of any plaintiff, and the plaintiffs’ June 10, 2011, Motion For Summary Judgment (docket no. 57) is **denied as moot**.

IT IS SO ORDERED.

DATED this 30th day of March, 2012.



MARK W. BENNETT
U. S. DISTRICT COURT JUDGE
NORTHERN DISTRICT OF IOWA