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

FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al.,	)	
Plaintiffs,	)	
v.	)	No. C 10-4018-MWB
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

REPLY IN SUPPORT OF UNITED STATES' MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

Nothing in Plaintiffs' Brief in Support of Resistance to Defendants' Motion to Dismiss ("Pls.' Opp'n" or "Resistance") shows they have standing to bring this action, their claims are ripe, or their request to enjoin enforcement action by the Food and Drug Administration ("FDA") is not foreclosed by *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950).[1] Despite these obvious failings, plaintiffs insist their claims must "be addressed now to resolve this dispute so that FDA and Plaintiffs can gain clarity on the application, scope and extent of [21 C.F.R. §§] 1240.61 and 131.110." Pls.' Opp'n at 17. Plaintiffs' unabashed demand for an advisory opinion should be rejected, especially where plaintiffs have steadfastly refused to use the avenue open to them for obtaining such an advisory determination: FDA's citizen petition process. 21 C.F.R. § 10.45(b).

[1] Plaintiffs now claim that "this is not a *Ewing*-type situation where [p]laintiffs are asking this Court to enjoin FDA from 'seizing' their raw milk," Pls.' Opp'n at 27, but this assertion is directly controverted by their Amended Complaint's prayer for "[a]n injunction enjoining any further enforcement, civil, criminal, administrative or otherwise, of [the regulations] against Plaintiffs." Am. Compl. at 26 ¶ G.

I. The Declaratory Judgment Act is Not Jurisdictional.

In their Resistance, Plaintiffs contend for the first time that "a declaratory judgment action gives Plaintiffs standing . . . ." Pls.' Opp'n at 10-11. Not so. "The operation of the Declaratory Judgment Act is procedural only. It creates a remedy in addition to actions seeking damages or injunctive relief, but does not provide an additional right of entry into federal courts." *Lawrence County v. South Dakota*, 668 F.2d 27, 29 (8th Cir. 1982) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-72 (1950)). Thus, it remains incumbent upon plaintiffs to demonstrate that this Court has subject matter jurisdiction over their claims. *See Cass County v. United States*, 570 F.2d 737, 740 (8th Cir. 1978). Plaintiffs have failed to meet their burden.

II. Plaintiffs' Claims Do Not Satisfy the *Abbott Laboratories* Ripeness Criteria.

Plaintiffs claim "the absence of any FDA enforcement action is irrelevant to whether Plaintiffs' declaratory judgment action is ripe for review." Pls.' Opp'n at 17-18. Although "a plaintiff need not always await the actual commencement of enforcement proceedings to challenge" a regulation, in order "for such an action to present a justiciable controversy, the threat of enforcement must have immediate coercive consequences of some sort upon the plaintiff." *Caldwell v. Gurley Ref. Co.*, 755 F.2d 645, 650 (8th Cir. 1985). Such was the case in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), where the challenged regulation "require[d] an immediate and significant change in the plaintiffs' conduct of their affairs," forcing them to "invest heavily" to comply. *Id.* at 152-53. Unlike the present action, both FDA and the plaintiffs in *Abbott Laboratories* agreed that the issue was "a purely legal one," the Court found that the regulations were "directed at [the plaintiffs] in particular," and FDA "represented

to the District Court that immediate compliance with their terms was expected." *Id.* at 152, 154. Here, it is by no means clear that 21 C.F.R. §§ 131.110 and 1240.61 even touch plaintiffs' alleged conduct. *See* Pls.' Opp'n at 53-56 (offering a number of arguments in support of their position that the regulations do not apply to plaintiffs).

The present case is akin to *Toilet Goods Association v. Gardner*, 387 U.S. 158 (1967), which the Supreme Court decided on the same day as *Abbott Laboratories*. The *Toilet Goods* Court observed it had "no idea whether or when" the challenged FDA regulation would be enforced "and what reasons the Commissioner will give to justify his order." 387 U.S. at 163. Judicial review was, therefore, "likely to stand on a much surer footing in the context of a specific application of th[e] regulation than . . . in the framework of [a] generalized challenge." *Id.* at 164. The Court reached this conclusion even though there was "no question" that FDA's regulation constituted final agency action and the challenge to it was "a purely legal question . . . that courts have occasionally dealt with without requiring a specific attempt at enforcement or exhaustion of administrative remedies." *Id.* at 162-63 (internal citations omitted). Just as in *Toilet Goods*, the present dispute requires additional factual development—whether through plaintiffs' submission of a citizen petition or an FDA investigation and enforcement action—before this Court could have sufficient information to determine whether the challenged regulations even apply to plaintiffs' conduct.

III. Neither FDA's Promulgation of the Regulations Nor Plaintiffs' Affidavits Establish the Final Agency Action Necessary for an As-Applied Challenge.

Plaintiffs insist that 21 C.F.R. §§ "1240.61 and 131.110 both constitute final agency action," as they "have been in existence for 21 and 37 years respectively." Pls.' Opp'n at 21. This argument reflects plaintiffs' fundamental misunderstanding regarding

the final agency action that is necessary in order for their claims to be ripe. If plaintiffs were bringing a direct challenge to the regulations themselves, the fact that the regulations have been promulgated in final form would be relevant. But in their opposition brief, plaintiffs expressly disavow such a challenge, stating that they "are not seeking to amend, modify or vacate 1240.61 and 131.110. Instead, [p]laintiffs are seeking a declaration that these regulations are unconstitutional *as applied to their conduct*." *Id.* at 33 (emphasis added). Because FDA has not yet had cause to consider whether its regulations even apply to plaintiffs' purported conduct, there is no final agency action with respect to the *application* of the challenged regulations. *But see* 21 C.F.R. § 10.45(d) (indicating that FDA's decision on a citizen petition regarding the scope of its regulations constitutes final agency action).

Nevertheless, plaintiffs repeatedly assert that "FDA has in fact taken the position that it is illegal for an individual to take raw milk across state lines" and "that it is illegal for dairy farmers to make raw milk 'available' for distribution across state lines." Pls.' Opp'n at 10. Missing from plaintiffs' brief is a single citation to any official FDA document in which the agency has *ever* so interpreted its regulations. Instead, plaintiffs cite to the affidavits of two lawyers who claim to have counseled clients "on raw milk issues" and who purport to be "familiar with and have personal knowledge of the general position of the [FDA] on raw milk." Kennedy Aff. ¶ 8; *see also* Bemis Aff. ¶ 22 ("Based on my dealings with FDA over the past three years, it is FDA's interpretation and application of the law that . . . ."). The self-serving and undocumented opinions of those who oppose FDA's regulations do not constitute an authoritative agency position.

Cf. Smiley v. Citibank, 517 U.S. 735, 742-43 (1996) (finding that statements authored by an agency's own lawyers were "too informal" to "establish binding agency policy").

Plaintiffs rely on FDA Warning Letters to individuals who are not plaintiffs in this case and whose actions differ significantly from the plaintiffs' purported conduct. Their reliance sheds no light on the application of FDA's regulations to plaintiffs. *See* Kennedy Aff., Attach. A (citing the recipient for distributing unpasteurized milk contaminated with *E. coli*); Bemis Aff., Attach. A (citing the recipient for commercial distribution of unpasteurized milk across state lines). Equally unavailing are the bizarre allegations of plaintiff Eric Wagoner, who claims that although his truck was "searched and seized by officials from Georgia," he destroyed the unpasteurized milk inside under orders from "FDA without a warrant or other legal process." Wagoner Aff. ¶¶ 8, 10.[2] Because Mr. Wagoner's "alleged facts" are "nothing more than unsupported conclusions, unwarranted inferences and sweeping legal conclusions," this Court is "not required to accept [them] as true" for purposes of this motion to dismiss. *Monson v. DEA*, 589 F.3d 952, 961-62 (8th Cir. 2009) (citation and quotation marks omitted).

CONCLUSION

For the foregoing reasons, defendants respectfully request that this Court dismiss this case for lack of jurisdiction over the subject matter or, in the alternative, failure to state a claim upon which relief can be granted.

[2] Had FDA actually ordered the destruction of the milk as alleged, which FDA may accomplish by means of the Food, Drug, and Cosmetic Act's *in rem* seizure provision, 21 U.S.C. § 334, the proper venue in which to object would have been in the seizure action itself, wherein Mr. Wagoner would have had "an opportunity to appear as a claimant and to have a full hearing before the court." *Ewing*, 339 U.S. at 598.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2010,
I electronically filed the foregoing with the
Clerk of the Court using the ECF system
which will send notification of such filing to
the parties or attorneys of record.

BY: /s/ ROGER GURAL