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.	)	

DEFENDANTS' COMBINED RESPONSE TO PLAINTIFFS' AMENDED BRIEFS IN SUPPORT OF SUMMARY JUDGMENT AND RESISTANCE TO FDA'S RENEWED MOTION TO DISMISS

The Food and Drug Administration ("FDA") learned from an Internet posting that a group of raw milk consumers planned to protest at FDA headquarters on November 1, 2011, because they mistakenly believed that their activities solely as consumers of raw milk might lead the government to take enforcement action against them. In response, FDA posted a statement on its website (the "November Statement") to help the protesters and others understand FDA's positions on the established risks associated with consuming raw milk and the enforcement of 21 C.F.R. § 1240.61 against individuals who transport raw milk across state lines solely for personal consumption. *See* Nov. Statement (DR[1] 67-1 Ex. A). In the November Statement, FDA set forth its position on how it would exercise its enforcement discretion with respect to consumers, stating, "[w]ith respect to the interstate sale and distribution of raw milk, the FDA has

[1] "DR" refers to the docket report.

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*." *Id.* (emphasis added).

In their latest filings, plaintiffs allege that this statement represents a break from past policies. *See* Pls.' Mots. to Amend & Suppl. Their Brs. in Supp. of Mot. for Summ. J. & Resist. to Defs.' Mot. to Dismiss at 2 ("Pls.' Amends.") (DR 67, 68). Plaintiffs are wrong. The November Statement reflects *precisely* the position that FDA articulated in its letter of March 16, 2011, a copy of which was filed with the Court. *See* Defs.' Status Report of March 16, 2011, (DR 43-1 Ex. A) (the "Administrative Determination").

In responding to questions referred to it by this Court, FDA made clear in the Administrative Determination that it "has *never* sought to bring an enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her personal consumption." *Id*. at 6 (emphasis in original). With respect to the future, FDA stated that it "has *no present intent* to alter significantly its raw milk-related enforcement activities. Producers and distributors of raw milk will remain subject to regulatory action, but it is highly unlikely that FDA would ever bring an enforcement action directly against a person who carried raw milk across state lines solely for his or her personal consumption." *Id.* at 7 (emphasis added). FDA emphasized this point again later: "FDA has not brought enforcement actions against individual consumers in the past and, subject to the considerations described [ ], *has no present intent* to do so in the future." *Id.* at 9 (emphasis added). The considerations described included whether a consumer is "found to frequently distribute raw milk to others, such that the 'consumer' would be more aptly described as a 'distributor.'" *Id.* at 7.

FDA's positions in the November Statement and the Administrative Determination regarding its enforcement policy as to consumers are indistinguishable and clear: FDA does not intend to refer enforcement actions against individuals who transport raw milk across state lines solely for person consumption, but it "intends to continue to direct its limited resources to enforcement actions against those who produce and/or distribute raw, unpasteurized milk in interstate commerce." *See* Admin. Determination at 9; *see also* Nov. Statement.

Thus, plaintiffs' argument that the November Statement constitutes a "tacit recognition" that enforcement of 21 C.F.R. § 1240.61 would be unlawful is wrong. *See* Pls.' Amends. at 2. The Administrative Determination and defendants' prior briefs in this case explain clearly why any transportation of raw milk across state lines violates 21 C.F.R. § 1240.61.[2] Moreover, the November Statement does not address the text of the regulation, but rather how FDA will *enforce* that regulation. *See* Nov. Statement. Likewise, plaintiffs' argument that the November Statement is a "tacit admission" that raw milk poses "no public health risk" is not tethered to reality. *See* Pls.' Amends. at 2. The Administrative Determination, the Administrative Record filed in this case (DR 49), and the November Statement all describe the health risks related to consuming raw milk. *See, e.g.*, Admin. Determination at 2-4; Nov. Statement (devoting three of its seven paragraphs to the public health risks of consuming raw milk).

Ultimately, plaintiffs' arguments boil down to the flawed theory that, unless FDA enforces 21 C.F.R. § 1240.61 against *every* possible violator in *every* circumstance, the decision to take *any* action against a violator is "arbitrary and capricious and irrational."

[2] *See* Admin. Determination at 4-6; Defs.' Renewed Mot. to Dismiss & Mot. for Summ.

See Pls.' Amends. at 3. But FDA's approach is rational precisely because it is based on a careful prioritization of agency resources and competing public health risks. As FDA stated in the Administrative Determination:

> Despite [its] clear and broad regulatory authority over the introduction of raw milk into interstate commerce, the Agency has consistently exercised its enforcement discretion with respect to consumers. . . . In so doing, FDA has never sought to bring an enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her personal consumption. Among other reasons, it would not constitute an efficient use of Agency resources to focus on end-users and consumers. This is true not only with respect to raw milk, but generally also with other products regulated by FDA.

Admin. Determination at 6. This position reflects an unquestionably reasonable exercise of the government's enforcement discretion.[3]

As set forth in prior filings, FDA's intentions with respect to consumers are relevant to this litigation for at least two reasons. First, the fact that FDA has not referred or threatened enforcement actions against consumers establishes that the "consumer-plaintiffs"[4] are bringing a *facial* challenge to 21 C.F.R. § 1240.61. *See* Defs.' Renewed Mot. to Dismiss & Mot. for Summ. J. at 16 (DR 51). Second, because *bona fide* consumers are not threatened with enforcement proceedings, it is not necessary for this Court to reach the consumer-plaintiffs' Constitutional claims. *See id.* at 43-44.

The consumer-plaintiffs previously claimed to live in constant fear of an enforcement action. *See id.* at 16. The November Statement is further and more recent

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J. at 6-7 (DR 51); Defs.' Br. in Resist. to Pls.' Mot. for Summ. J. at 13-18 (DR 62).

[3] In *Heckler v. Chaney*, 470 U.S. 821 (1985), the Supreme Court held that FDA's decision whether or not to engage in enforcement "is . . . not subject to judicial review" because "agency refusals to institute investigative or enforcement proceedings" are "committed to agency discretion." *Chaney*, 470 U.S. at 837-38; 5 U.S.C. § 701(a)(2).

[4] The "consumer-plaintiffs" are plaintiffs Donnelly, Allen, Miller, Heckman, and Rose.

evidence that these claimed fears are baseless. Because the consumer-plaintiffs are not "*in immediate danger* of sustaining some direct injury as a result of the challenged statue or official conduct," *see* Memorandum and Opinion Order Regarding Defendants' Motion to Dismiss at 41 (DR 27) (citing *Pub. Water Supply Dist. No. 10 of Cass County, Mo. v. City of Peculiar, Mo*., 345 F.3d 570, 573 (8th Cir. 2003) (emphasis in original)), plaintiffs' new filings demonstrate only that the consumer-plaintiffs' claims are unripe.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that I electronically served a copy of the foregoing document to which this certificate is attached to the parties or attorneys of record, shown below, on November 15, 2011.

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