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. 5:10-cv-4018-MWB
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

JOINT STATUS REPORT

Pursuant to the Court's Order of August 18, 2010, the parties hereby submit this Joint Status Report. In the Court's Memorandum Opinion and Order Regarding Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim Upon Which Relief Can Be Granted ("Order") issued on the same day, the Court observed that there were "questions ante to the plaintiffs' constitutional claims" regarding whether "plaintiffs' conduct falls within the proscriptions of [21 C.F.R.] § 1240.61," and that a resolution of these questions "might, in turn, resolve finally the questions about the plaintiffs' standing and the ripeness of their claims . . . ." Order at 52-53. The Court noted that the questions could properly "fall within the scope of a citizen petition pursuant to [21 C.F.R.] § 10.25, if presented as a request that the FDA take administrative action to interpret the authorizing statutes and regulations." *Id.* at 52.

Plaintiffs have proposed that, in lieu of plaintiffs filing a citizen petition under 21 C.F.R. § 10.25(a), the Court exercise its discretion to temporarily stay this matter and

refer these preliminary questions to FDA for an initial administrative determination under the doctrine of primary jurisdiction, a procedure contemplated by 21 C.F.R. § 10.25(c). *See, e.g.*, *Reiter v. Cooper*, 507 U.S. 258, 268-269 (1993); *Mitchell Coal & Coke Co. v. Pennsylvania R. Co.*, 230 U.S. 247, 267 (1913); *United States v. Rice*, 605 F.3d 473, 475 (8th Cir. 2010); *Access Telecomms. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998). Defendants have agreed that the Commissioner of Food and Drugs would accept such a referral from the Court pursuant to 21 C.F.R. § 10.60(b) and will furnish a response as soon as possible but no later than 180 days of the referral.[1] *Cf.* 21 C.F.R. § 10.30(e)(2) (requiring FDA to furnish a response to a citizen petition within 180 days). Accordingly, the parties request that the Court exercise its authority to refer the following questions to FDA for an initial administrative determination:

> [W]hether [21 C.F.R.] § 1240.61 applies to and proscribes the conduct of
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> (1) persons who travel from one state, where it is not legal to purchase raw milk, to another state, where it is legal to purchase raw milk, legally purchase raw milk, then return to the original state where they consume the raw milk themselves or give it to their friends or family members; or
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> (2) a principal and agent who agree that the agent will obtain raw milk out-of-state, where it is legal to do so, and to deliver it to the principal in the principal's home state, where sales of raw milk are not permitted, [where the principal then consumes the raw milk or gives it to their friends or family members]; or

[1] Defendants would also agree to take administrative action to interpret 21 C.F.R. § 1240.61 with respect to the same three questions if raised by plaintiffs in a citizen petition filed pursuant to 21 C.F.R. § 10.25(a).

(3) a producer of raw milk who sells raw milk in [a state where it is legal to do so in] an intrastate transaction to persons that he knows are from out of state.

Attached is a Proposed Order referring these questions to FDA for an initial administrative determination.

Respectfully submitted,

/s/
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