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, CYNTHEA 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

ORDER LIFTING STAY AND SETTING SUPPLEMENTAL BRIEFING SCHEDULE

This case is before the court on the defendants' March 16, 2011, Status Report (docket no. 43) and the plaintiffs' March 17, 2011, Status Report (docket no. 44). Both sides advise the court that the Food and Drug Administration (FDA) has now issued an initial administrative determination on the three questions referred to the FDA by the court in its September 17, 2010, Order Regarding The Parties' Joint Status Report And Request For Referral Of Questions To The FDA For Initial Administrative Determination (docket

no. 29). The defendants suggest that the most economical and expeditious way to reach a final disposition of this case, in light of the FDA's initial administrative determination, is for the parties to file supplemental briefs on issues that the court left unresolved in its August 18, 2010, 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 (docket no. 27) or to file motions for summary judgment on the merits of the plaintiffs' claims. The plaintiffs counter that the FDA's admissions, in its initial administrative determination, provide the court with enough facts to rule on the constitutional claims brought by the plaintiffs in their First Amended Complaint, so that no further briefing is necessary. The plaintiffs request that the court simply render a final decision on all issues in the defendants' motion to dismiss, without further delay that might enable the defendants to reformulate their arguments. Implicit in the parties' status reports is agreement that the stay on proceedings in this action should be lifted.

The court agrees with the parties that the stay should be lifted and that this case should proceed toward final disposition. The court also agrees with the defendants that supplemental briefing and perhaps additional dispositive motions are appropriate, in light of the FDA's initial administrative determination, and are likely to lead to the expeditious, economical, and just determination of the issues presented in this case.

THEREFORE,

- 1. The **stay** on proceedings in this court, entered in the August 18, 2010, Memorandum Opinion And Order (docket no. 27), and extended in the September 17, 2010, Order (docket no. 29), **is lifted**.
- 2. The defendants shall have **to and including April 18, 2011**, to file the administrative record with respect to the adoption of 21 C.F.R. § 1240.61 and § 131.110.

3. Deadlines for supplemental briefing and motions are set as follows:

a. The defendants shall have to and including May 11, 2011, to file a

supplemental brief in support of their April 26, 2010, Motion To Dismiss (docket

no. 10) or, in the alternative, to move for summary judgment regarding the merits

of the plaintiffs' pre-enforcement challenges to 21 C.F.R. § 1240.61 and § 131.110

under the Administrative Procedure Act, 5 U.S.C. § 701 et seq., and to present any

affirmative defenses.

b. The plaintiffs shall have to and including June 10, 2011, to file a

supplemental resistance to the defendants' Motion To Dismiss, to respond to any

motion for summary judgment by the defendants, or to file any motion for summary

judgment.

c. The defendants shall have to and including July 1, 2011, to file a

supplemental reply in support of their Motion To Dismiss and to resist any

summary judgment motion by the plaintiffs.

d. The plaintiffs shall have to and including July 15, 2011, to file any

reply in support of any motion for summary judgment filed pursuant to paragraph

3.b.

IT IS SO ORDERED.

DATED this 1st day of April, 2011.

MARK W. BENNETT

U. S. DISTRICT COURT JUDGE

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NORTHERN DISTRICT OF IOWA

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