

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' RENEWED MOTION TO DISMISS AND, IN THE ALTERNATIVE,
MOTION FOR SUMMARY JUDGMENT**

COME NOW defendants Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services, the United States Department of Health and Human Services ("HHS"), and Margaret Hamburg, Commissioner of Food and Drugs, United States Food and Drug Administration ("FDA"), who respectfully renew their Motion to Dismiss Plaintiffs' Amended Complaint (DR 10) pursuant to Federal Rule of Civil Procedure 12(b)(6) and Local Rule 7. In the alternative, pursuant to Local Rules 7 and 56, and Federal Rule of Civil Procedure 56, defendants move this Court to enter summary judgment in favor of defendants on all claims.

Defendants' renewed motion to dismiss should be granted because plaintiffs have failed to state a claim upon which relief can be granted. In support of their renewed motion, defendants refer to Section IV.B of their Brief in Support of United States' Motion to Dismiss Plaintiffs' Amended Complaint (DR 11), filed on April 26,

2010.¹ Defendants refer also to Section VI in the accompanying Brief in Support of Defendants' Renewed Motion to Dismiss Plaintiffs' Amended Complaint, and, in the Alternative, for Summary Judgment; and Brief on the Merits in Support of FDA's Promulgation of Challenged Regulations ("Brief"), which contains the supplemental briefing provided for in the Court's Order Lifting Stay and Setting Supplemental Briefing Schedule (DR 45), dated April 1, 2011, ("Order").

Defendants' motion in the alternative for summary judgment should be granted because there are no genuine issues of material fact with respect to defendants' statute of limitations affirmative defense. In support of this motion in the alternative, defendants refer to Section IV of the accompanying Brief, together with Defendants' Statement of Material Facts and Defendants' Appendix in Support of Defendants' Motion for Summary Judgment.

Defendants also contend that plaintiffs' claims under the Administrative Procedures Act ("APA") should be denied. In accordance with the Order, on April 18, 2011, defendants filed the administrative record setting forth the bases for FDA's promulgation of the regulations challenged by plaintiffs. Section V of the Brief constitutes defendants' briefing on the merits in connection with the administrative record. In accordance with Local Rule 56(i), however, this briefing on the merits is separate and apart from defendants' motions, and provides an independent basis upon which to resolve the APA claims in favor of defendants.

¹ In its Memorandum and Opinion Order Regarding defendants' Motion to Dismiss (DR 27) the Court denied without prejudice defendants' challenges to subject matter jurisdiction, denied defendants' administrative exhaustion claims, and reserved ruling on whether plaintiffs' complaint failed to state a claim upon which relief can be granted. *See id.* at 25.

WHEREFORE, defendants respectfully request that the Court grant their renewed motion to dismiss plaintiffs' Amended Complaint, or, in the alternative, grant their motion for summary judgment. Defendants also respectfully request that the Court consider their briefing on the merits with respect to plaintiffs' APA claims, and that this Court grant such further relief as it deems proper under the circumstances.

Respectfully submitted,

STEPHANIE M. ROSE
United States Attorney

Lawrence D. Kudej
Assistant United States Attorney
401 First St. SE, Suite 400
Cedar Rapids, IA 52401-1825
319-363-6333
319-363-1990 (fax)
Larry.Kudej@usdoj.gov

By: /s/ Roger Gural
ROGER GURAL
Trial Attorney
Office of Consumer Protection Litigation
Department of Justice
Civil Division
P.O. Box 386
Washington, D.C. 20044
202-307-0174
202-514-8742 (fax)
roger.gural@usdoj.gov

Of Counsel:
WILLIAM B. SHULTZ
Acting General Counsel

RALPH S. TYLER
Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

THOMAS J. COSGROVE
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
10903 New Hampshire Avenue
Building 32, Room 4330
Silver Spring, MD 20993-0002
(301) 796-8613

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 May 11, 2011.

UNITED STATES ATTORNEY

BY: s/ Roger Gural

COPIES TO:

David G. Cox (OH Sup. Ct. No. 0042724)
4240 Kendale Road
Columbus, OH 43220

Wallace L. Taylor
118 3rd Avenue, S.E.
Cedar Rapids, IA 52401-1210