

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' STATEMENT OF MATERIAL FACTS

The United States Department of Health and Human Services (“HHS”), Kathleen Sebelius, in her official capacity as Secretary of HHS, and Margaret Hamburg, Commissioner of Food and Drugs, United States Food and Drug Administration (“FDA”) (collectively, “defendants”) submit the following as their Statement of Material Facts.

1. FDA promulgated the Milk Standard of Identity Regulation, 21 C.F.R. § 131.110, on October 10, 1973. 38 Fed. Reg. 27924 (Oct. 10, 1973). App. 39.
2. FDA promulgated their Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 21 C.F.R. § 1240.61, (“The PHSA Regulation”) on August 10, 1987. 52 Fed. Reg. 29509 (Aug. 10, 1987). App. 41.
3. Plaintiffs filed the instant action, Civ. No. 10-04018 (N.D. Iowa), on February 20, 2010. App. 43.

4. On Thursday, October 15, 2009, an investigator for the Georgia Department of Agriculture (“GDA”) arrived at Athens Free Market, a farmer’s market in Athens, Georgia to investigate the allegation of illegal meat sales. App. 32, ¶¶ 2-3.

5. While conducting this investigation, the GDA inspector noticed Eric Wagoner unloading gallon jugs of milk from coolers that were on Mr. Wagoner’s truck. App. 32, ¶ 3.

6. The investigator inspected the milk jugs, and determined that they contained unpasteurized milk from South Carolina. App. 32, ¶ 3; *cf.* App. 25, ¶ 6.

7. All of the unpasteurized milk (the “Embargoed Milk”) on Mr. Wagoner’s truck, (totaling 110 gallons) was placed under a Stop Sale Order (embargo) and the GDA investigator advised Mr. Wagoner it is illegal under Georgia law to sell unpasteurized milk for human consumption in the State of Georgia. App. 32, ¶ 4; *cf.* App. 25, ¶ 8.

8. At the time the Embargoed Milk was placed under embargo, the GDA investigator gave a Stop Sale notice to Mr. Wagoner and placed tags on each cooler. App. 32, ¶ 6; *see also* App. 35, 37 (photographs of cooler and Stop Sale notices).

9. Mr. Wagoner agreed to voluntarily destroy the Embargoed Milk. App. 32, ¶ 5.

10. Because a place to destroy the Embargoed Milk could not be found, Mr. Wagoner asked that he be allowed to transport it to his home for destruction on the following Monday. This permission was granted by GDA. App. 32, ¶ 5; *cf.* App. 25, ¶ 9.

11. On Friday, October 16th, 2009, FDA received a telephone call from Peggy Gates, Director for the Dairy Division at GDA. App. 28, ¶ 3.

12. Ms. Gates informed FDA that a meat compliance officer from GDA had placed an embargo on 110 gallons of raw milk intended for human consumption at the Athens Free Market. App. 28, ¶ 3.

13. At no time on Friday or over the following weekend did anyone from FDA have contact with Mr. Wagoner, who had possession of the embargoed the raw milk. App. 28, ¶ 4.

14. At no time on Friday or over the following weekend did anyone from FDA have any contact with anyone else associated with Mr. Wagoner or Athens Locally Grown. App. 28, ¶ 4.

15. On Monday, October 19, 2009, Ms. Gates and a GDA investigator drove to Mr. Wagoner's residence. App. 32, ¶ 7.

16. Marybeth Willis, a Regional Milk Specialist in FDA's Southeast Regional Office, in Atlanta, Georgia, met Ms. Gates and her colleague at approximately 1:00 pm on October 19th, and the three then proceeded to Mr. Wagoner's home. App. 28, ¶ 1; 29, ¶ 6; *see* App. 32, ¶ 7.

17. Ms. Willis accompanied the GDA officials to Mr. Wagoner's residence to observe and collect information on behalf of FDA. App. 29, ¶ 6; App. 32, ¶ 7.

18. After Ms. Gates, the GDA investigator, and Ms. Willis arrived at Mr. Wagoner's residence, Mr. Wagoner voluntarily dumped the Embargoed Milk on the ground. App. 32, ¶ 7; App. 29, 8; *cf.* App. 26, ¶¶ 12-13 (youtube videos of Mr. Wagoner and his associates dumping the Embargoed Milk onto the ground).

19. At no time did Ms. Willis, or anyone else from FDA, order or otherwise direct Mr. Wagoner to destroy the Embargoed Milk or take any other action. App. 29, ¶ 9; *cf.* App. 26, ¶¶ 12-13 (youtube videos of Mr. Wagoner and his associates dumping the Embargoed Milk onto the ground).

20. While at Mr. Wagoner's residence Ms. Willis answered questions that were directed to her by those congregated on Mr. Wagoner's property. If asked about the requirements of federal law with respect to raw milk, Ms. Willis would have responded that federal regulations prohibit the delivery of raw milk into interstate commerce. App. 29, ¶ 9; *cf.* App. 26, 15-16.

21. Ms. Willis did not, however, issue any order or direction to anyone on this or any other basis. App. 29, ¶ 9.

22. Mr. Wagoner did not challenge the embargo in court, as was his right under Georgia law. App. 33, ¶ 8; App. 29, ¶ 8.

23. The embargo described above was carried out entirely by GDA under the authority of Georgia law. App. 33, ¶ 8; App. 33, ¶ 9 (citing GEORGIA CODE. ANN. § 26-2-242 (prohibiting the sale of unpasteurized milk for human consumption in the State of Georgia) and GEORGIA CODE. ANN. § 26-2-244(a) (prohibiting the shipment unpasteurized milk for human consumption into Georgia from another state)).

24. FDA played no role in the embargo of the Embargoed Milk and/or the discussions with Mr. Wagoner leading up to his decision to voluntarily destroy the Embargoed Milk. App. 28, ¶ 4; App. 33, ¶¶ 8-9; *see* App. 29, ¶¶ 9-10; *cf.* App. 25, ¶ 8.

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:

SALLY A. HOWARD
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