

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’ RESPONSE TO PLAINTIFFS’ STATEMENT OF MATERIAL FACTS

The United States Department of Health and Human Services (“HHS”), Kathleen Sebelius, as Secretary of HHS, and Margaret Hamburg, Commissioner of Food and Drugs, United States Food and Drug Administration (“FDA”) in their official capacities (collectively, “defendants”) submit the following as their Response to Plaintiffs’ Statement of Material Facts (DR 57¹, Attach. 1).

A. General Response

Plaintiffs moved for summary judgment on five grounds addressing the merits of 21 C.F.R. §§ 1240.61 and 131.110. Pls.’ Mot. for Summ. J. (DR 57). Each of these grounds is inappropriate for disposition through summary judgment. *See Thomas v. E.P.A.*, No. 06-CV-115-LRR, 2007 WL 2127881, *1 (N.D. Iowa July 23, 2007) (citing LR 56; *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1579-80 (10th Cir. 1994) (finding the district court’s use of summary judgment supported by a statement of

¹ “DR” refers to the docket report.

undisputed facts was “inconsistent with the standards for review of agency action under the APA” and “invites (even requires) the reviewing court to rely on evidence outside the administrative record”) (internal footnote omitted)).² Further, plaintiffs’ accompanying Statement of Material Facts does not contain a single citation to the filed administrative record (DR 49) underlying the promulgation of 21 C.F.R. §§ 1240.61 and 131.110.

Hence, defendants generally object to plaintiffs’ Statement of Material Facts because:

(1) defendants will be required to respond to alleged facts that are outside of the administrative record filed in this case; (2) summary judgment is inappropriate for reviewing the merits of an administrative regulation; and (3) plaintiffs’ alleged facts are largely irrelevant to any issues that could be resolved upon summary judgment. In this case limited to review of an administrative record, defendants attempt to address each individual statement of material fact below pursuant to LR 56.b.2.

B. Individual Responses

- 1 - 54. Defendants are without knowledge or information sufficient to form a belief as to the truth of paragraphs 1 through 54 and so deny them. Defendants object to paragraphs 1 through 54 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
55. Defendants admit that officials from the Georgia Department of Agriculture (“GDA”) embargoed unpasteurized milk and ordered its destruction. Defs.’ App. 32, ¶¶ 2-6. At no time did anyone from FDA order or otherwise direct Plaintiff Wagoner to destroy the embargoed raw milk or take any other action. Defs.’ App. 29, ¶ 9; Defs.’ App. 33, ¶¶ 8-9.

² Defendants’ Motion for Summary Judgment (DR 50) and their accompanying Statement of Material Facts were confined to a narrow statute of limitations issue which may be appropriately resolved through summary judgment. See 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 the Challenged Regulations (DR 50) (“Combined Brief”) at Section IV. Defendants addressed plaintiffs’ challenges to 21 C.F.R. §§ 1240.61 and 131.110 in defendants’ brief on the merits. *Id.* at Sections V, VI.

- 56 - 139. Defendants are without knowledge or information sufficient to form a belief as to the truth of paragraphs 56 through 139 and so deny them. Defendants object to paragraphs 56 through 139 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
140. Defendants admit that officials from the GDA placed Plaintiff Wagoner's unpasteurized milk under a Stop Sale Order and advised Plaintiff Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Defs.' App. 32, ¶¶ 2-6. At no time did anyone from FDA order or otherwise direct Plaintiff Wagoner to destroy the embargoed raw milk or take any other action. Defs.' App. 29, ¶ 9; Defs.' App. 33, ¶¶ 8-9.
- 141 - 152. Defendants are without knowledge or information sufficient to form a belief as to the truth of paragraphs 141 through 152 and so deny them. Defendants object to paragraphs 141 through 152 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
153. Defendants admit that officials from the GDA, not FDA, inspected Plaintiff Wagoner's truck and discovered unpasteurized milk. Defs.' App. 32, ¶ 3. Defendants are without knowledge or information sufficient to form a belief as to the remainder of paragraph 153 and so deny it. Defendants also object to the remainder of paragraph 153 as it will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
154. Defendants admit that officials from the GDA placed Plaintiff Wagoner's unpasteurized milk under a Stop Sale Order and advised Plaintiff Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Defs.' App. 32, ¶¶ 2-6. At no time did anyone from FDA order or otherwise direct Plaintiff Wagoner to destroy the embargoed raw milk or take any other action. Defs.' App. 29, ¶ 9; Defs.' App. 33, ¶¶ 8-9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 154 and so deny it. Defendants object to the remainder of paragraph 154 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.

155. Defendants admit officials from the GDA advised Plaintiff Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Defs.' App. 32, ¶¶ 2-6. Defendants admit Plaintiff Wagoner asked that he be allowed to transport it to his home for destruction the following Monday and he was granted permission to do so by the GDA. Defs.' App. 32, ¶ 5. At no time did anyone from FDA order or otherwise direct Plaintiff Wagoner to destroy the embargoed raw milk or take any other action. Defs.' App. 29, ¶ 9; Defs.' App. 33, ¶¶ 8-9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 155 and so deny it. Defendants object to the remainder of paragraph 155 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
156. Defendants admit officials from the GDA advised Plaintiff Wagoner the milk needed to be voluntarily destroyed. Defs.' App. 32, ¶ 5. Defendants admit Marybeth Willis of the FDA accompanied officials from the GDA to observe the destruction on behalf of FDA. Defs.' App. 29, ¶ 6. While at Plaintiff Wagoner's residence Willis politely answered questions that were directed to her by those congregated on Plaintiff Wagoner's property. Defs.' App. 29, ¶ 9. If asked about the requirements of federal law with respect to raw milk, Willis would have responded that federal regulations prohibit the delivery of raw milk into interstate commerce. *Id.* Willis did not, however, issue any order or direction to anyone on this or any other basis. *Id.* At no time did Willis, or anyone else from FDA, order or otherwise direct Mr. Wagoner to destroy the embargoed raw milk or take any other action. *Id.*; Defs.' App. 33, ¶¶ 8-9. Willis would have had no authority to order Mr. Wagoner to destroy the embargoed raw milk. Defs.' App. 29, ¶ 10. Only the United States Department of Justice ("DOJ") has the authority to initiate a judicial proceeding that could result in a seizure, and, to Willis' knowledge, no such proceeding was ever initiated with respect to the embargoed raw milk in Mr. Wagoner's possession. *Id.* Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 156 and so deny it. Defendants object to the remainder of paragraph 156 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.

157. Defendants admit that officials from the GDA placed Plaintiff Wagoner's unpasteurized milk under a Stop Sale Order and advised Plaintiff Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Defs.' App. 32, ¶¶ 2-6. At no time did anyone from FDA order or otherwise direct Plaintiff Wagoner to destroy the embargoed raw milk or take any other action. Defs.' App. 29, ¶ 9; Defs.' App. 33, ¶¶ 8-9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 157 and so deny it. Defendants object to the remainder of paragraph 157 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
158. Defendants object to paragraph 158 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
159. Defendants admit officials from the GDA advised Plaintiff Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Defs.' App. 32, ¶¶ 2-6. Defendants admit Plaintiff Wagoner asked that he be allowed to transport it to his home for destruction the following Monday and he was granted permission to do so by the GDA. Defs.' App. 32, ¶ 5. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 159 and so deny it. Defendants object to the remainder of paragraph 159 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
160. Defendants admit officials from the GDA advised Plaintiff Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. Defs.' App. 32, ¶¶ 2-6. Defendants admit Plaintiff Wagoner asked that he be allowed to transport it to his home for destruction the following Monday and he was granted permission to do so by the GDA. Defs.' App. 32, ¶ 5. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 160 and so deny it. Defendants object to the remainder of paragraph 160 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.

161. Defendants admit officials from the GDA advised Plaintiff Wagoner the milk needed to be voluntarily destroyed. Defs.' App. 32, ¶ 5. Defendants admit Marybeth Willis of the FDA accompanied officials from the GDA to observe the destruction and collect information on behalf of FDA. Defs.' App. 29, ¶ 6. While at Plaintiff Wagoner's residence Willis politely answered questions that were directed to her by those congregated on Plaintiff Wagoner's property. Defs.' App. 29, ¶ 9. If asked about the requirements of federal law with respect to raw milk, Willis would have responded that federal regulations prohibit the delivery of raw milk into interstate commerce. *Id.* Willis did not, however, issue any order or direction to anyone on this or any other basis. *Id.* At no time did Willis, or anyone else from FDA, order or otherwise direct Mr. Wagoner to destroy the embargoed raw milk or take any other action. *Id.*; Defs.' App. 33, ¶¶ 8-9. Willis would have had no authority to order Mr. Wagoner to destroy the embargoed raw milk. Defs.' App. 29, ¶ 10. Only DOJ has the authority to initiate a judicial proceeding that could result in a seizure, and, to Willis' knowledge, no such proceeding was ever initiated with respect to the embargoed raw milk in Mr. Wagoner's possession. *Id.* Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of paragraph 161 and so deny it. Defendants object to the remainder of paragraph 161 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
162. Admit.
163. Denied. The statements in paragraph 163 are plaintiffs' characterizations of FDA's March 16, 2011, letter to Gary Cox, and defendants respectfully refer the Court to that document for a full and complete statement of its contents. Pls.' App. 46.
164. Admit.
165. Denied. The statements in paragraph 165 are plaintiffs' characterizations of FDA's March 16, 2011, letter to Gary Cox, and defendants respectfully refer the Court to that document for a full and complete statement of its contents. Pls.' App. 47.
166. Denied. The statements in paragraph 166 are plaintiffs' characterizations of FDA's March 16, 2011, letter to Gary Cox, and defendants respectfully refer the Court to that document for a full and complete statement of its contents. Pls.' App. 47.
167. Denied. The statements in paragraph 167 are plaintiffs' characterizations of FDA's March 16, 2011, letter to Gary Cox, and defendants respectfully refer the Court to that document for a full and complete statement of its contents. Pls.' App. 47.

168. Denied. The statements in paragraph 168 are plaintiffs' characterizations of FDA's March 16, 2011, letter to Gary Cox, and defendants respectfully refer the Court to that document for a full and complete statement of its contents. Pls.' App. 47.
169. Denied. The statements in paragraph 169 are plaintiffs' characterizations of FDA's March 16, 2011, letter to Gary Cox, and defendants respectfully refer the Court to that document for a full and complete statement of its contents. Pls.' App. 48.
170. Defendants admit that certain FDA-approved drugs have side effects. However, defendants object to paragraph 170 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
171. Admit.
172. Defendants admit in 2007 there was a report that three individuals had sepsis attributed to *Listeria* and died close to the time of their acute illness onset. Pls.' App. at 233. Defendants respectfully refer the Court to that document for a full and complete statement of its contents. *Id.* at 232-35. Defendants object to paragraph 172 on the grounds that the statements therein will not affect the outcome of this suit under governing law and LR 56.i, Fed. R. Civ. P. 56(c)(2), and Fed. R. Evid. 401, 402, and 403.
173. Denied. The FoodNet Population Survey determined the prevalence and severity of gastrointestinal illness among persons within the FoodNet sites and not the prevalence and severity of gastrointestinal illness within the total U.S. population. Pls.' App. 266, 276.

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 July 1, 2011 July 1, 2011.

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BY: s/ Roger Gural

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