

**BEFORE THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA
WESTERN DIVISION**

Farm-to-Consumer	:	
Legal Defense Fund	:	Case No.
8116 Arlington Blvd, Suite 263	:	
Falls Church, VA 22042	:	
	:	Judge
and	:	
	:	
Laurie Donnelly	:	
427 8th Street	:	
Sloan, IA 51055	:	
	:	
and	:	
	:	
Jennifer Allen	:	
3603 Ramelle Dr.	:	
Council Bluffs, IA 51501	:	
	:	
and	:	
	:	
Dr. Joseph Heckman	:	
19 Forman Ave.	:	
Monroe, NJ 08831	:	
	:	
and	:	
	:	
Dane Miller	:	
198 Slater Rd.	:	
Reading, PA 19605	:	
	:	
and	:	
	:	
Cynthia Lee Rose	:	
415 N. Main Ave.	:	
Maiden, NC 28650	:	
	:	
and	:	
	:	
Eric Wagoner	:	
310 Woody Rd.	:	

Royston, GA 30662

and

**Anne Cooper
1104 Mill Pointe
Bogart, GA 30622**

and

**Michael Buck
d/b/a Butter Patch Jerseys
175 Dairy Lane
Saluda, SC 29138**

Plaintiffs

v.

**Kathleen Sebelius,
in her official capacity as Secretary,
United States Department of Health
and Human Services,
200 Independence Avenue, S.W.,
Sixth Floor,
Washington, D.C. 20201**

and

**United States Department of
Health And Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201**

and

**Margaret Hamburg,
in her official capacity as
Commissioner, United States
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002**

Defendants

**PLAINTIFFS' COMPLAINT FOR DECLARATORY, PRELIMINARY AND OTHER
INJUNCTIVE RELIEF**

Pursuant to Fed. Rule Civ. P. 57 and 65(a), Plaintiffs hereby file their Complaint seeking declaratory, preliminary and other injunctive relief. Plaintiffs allege as follows:

GENERAL ALLEGATIONS

Nature of the Action

1. This is an action brought by Plaintiffs Farm-to-Consumer Legal Defense Fund (the "Fund" or "FTCLDF") and several of its members under, in part, the Constitutional Right to Travel; the Constitutional Right of Privacy; the substantive due process clause of the Fifth Amendment of the United States Constitution; Article 1, Section 1 of the United States Constitution (the Separation of Powers/Non-delegation doctrine); and the Administrative Procedure Act ("APA"), 5 U.S.C. 701, *et seq.*

2. Plaintiffs seek to enjoin the enforcement of 21 CFR 1240.61 (hereinafter "1240.61") and 21 CFR 131.110 (hereinafter "131.110") against them by the Food and Drug Administration ("FDA") and also seek a declaration that 1240.61 and 131.110 are unconstitutional as applied against them. The legislative authority for and the specific language of these agency regulations are addressed below in Count One of this complaint.

3. A preliminary injunction is necessary at the appropriate time because Plaintiffs will suffer irreparable, actual harm if enforcement of 1240.61 and 131.110 is not enjoined. Specifically, the individual Plaintiffs have already decided that complying with 1240.61 and 131.110 violates their liberties including but not limited to their constitutional right to travel and their constitutional right of privacy, and also violates their rights to substantive due process.

The Parties

4. Plaintiff Fund is a non-profit organization organized under the laws of the State of Ohio. The Fund's principal place of business is located at 8116 Arlington Boulevard, Suite 263, Falls Church, Virginia 22042.

5. As of January 1, 2010, the Fund consisted of over 1,900 members from 49 different States.

6. Plaintiff Laurie Donnelly resides at 427 8th Street, Sloan, Woodbury County, Iowa.

7. It is illegal to sell raw milk in the State of Iowa even though it is legal to consume raw milk and raw dairy products in Iowa. However, it is legal to sell raw milk and cream in the State of Nebraska as long as the sale takes place at a dairy farm.¹

8. On more than one occasion in 2009, Plaintiff Donnelly drove from Iowa into Nebraska and legally purchased and obtained raw milk in final package form.

9. After legally purchasing raw milk from a dairy farm in Nebraska, Plaintiff Donnelly traveled back into Iowa in possession of the raw milk where she and her family then consumed the milk. This activity continues to this day.

10. Plaintiff Jennifer Allen resides at 3603 Ramelle Drive, Council Bluffs, Iowa.

11. It is illegal to sell raw milk and cream in the State of Iowa even though it is legal to consume raw milk and raw dairy products in Iowa. However, it is legal to sell raw milk and cream in the State of Nebraska as long as the sale takes place at a dairy farm.

¹ Some States allow the sale of raw milk and/or raw milk products (such as kefir, yogurt, butter, etc.); others prohibit the sale of raw milk and/or raw milk products. As of the filing of this Complaint, at least 28 States allow the *sale* of raw milk. However, the *consumption* of raw milk is legal in all 50 States.

12. On more than one occasion in 2009, Plaintiff Allen drove from Iowa into Nebraska and legally purchased and obtained raw milk and cream in final package form.

13. After legally purchasing raw milk and cream from a dairy farm in Nebraska, Plaintiff Allen traveled back into Iowa in possession of the raw milk and cream where she and her family then consumed the milk and cream. This activity continues to this day.

14. Plaintiff Dr. Joseph Heckman is a member of the Fund and resides at 19 Forman Avenue, Monroe, New Jersey.

15. It is illegal to sell raw milk in the State of New Jersey even though it is legal to consume raw milk and raw dairy products in New Jersey. However, it is legal to sell raw milk in the State of Pennsylvania as long as the seller is either a licensed dairy farm or a licensed retail store.

16. On more than one occasion in 2009, Plaintiff Heckman drove from New Jersey into Pennsylvania and legally purchased and obtained raw milk in final package form from a licensed dairy farm.

17. After legally purchasing raw milk from a licensed farm in Pennsylvania, Plaintiff Heckman traveled back into New Jersey in possession of the raw milk where he and his family then consumed the milk. This activity continues to this day.

18. Plaintiff Dane Miller resides at 198 Slater Road Reading, Pennsylvania and has relatives are located in the State of Virginia.

19. It is illegal to sell raw milk in the State of Virginia even though it is legal to consume raw milk and raw dairy products in Virginia. However, it is legal to sell raw

milk in the State of Pennsylvania as long as the seller is either a licensed dairy farm or a licensed retail store.

20. On more than one occasion in 2009, Plaintiff Miller drove from Virginia to Pennsylvania and legally purchased and obtained raw milk in final package form from a licensed dairy farm in Pennsylvania.

21. After legally purchasing raw milk from a licensed farm in Pennsylvania, Plaintiff Miller traveled from Pennsylvania into Virginia in possession of the raw milk, where he and his relatives then consumed the milk. This activity continues to this day.

22. Plaintiff Cynthea Lee Rose resides at 415 North Main Avenue, Maiden, North Carolina.

23. It is illegal to sell raw milk in the State of North Carolina even though it is legal to consume raw milk and raw dairy products in North Carolina. However, it is legal to sell raw milk in the State of South Carolina as long as the seller is a licensed dairy farm or a licensed retail store.

24. On more than one occasion in 2009, Plaintiff Rose drove from North Carolina into South Carolina and legally purchased and obtained raw milk in final package form.

25. After legally purchasing raw milk from a licensed farm in South Carolina, Plaintiff Rose traveled back into North Carolina in possession of the raw milk where she and her family then consumed the milk. This activity continues to this day.

26. Plaintiff Eric Wagoner is a member of the Fund and resides at 310 Woody Road, Royston, Georgia 30662.

27. It is illegal to sell raw milk for human consumption in the State of Georgia even though it is legal to consume raw milk and raw dairy products in Georgia. However, it is legal to sell raw milk in the State of South Carolina as long as the seller is either a licensed dairy farm or a licensed retail store.

28. On more than one occasion in 2009, Plaintiff Wagoner drove from Georgia to South Carolina and legally purchased and obtained raw milk in final package form.

29. After legally purchasing raw milk from a licensed farm in South Carolina, Plaintiff Wagoner traveled back into Georgia in possession of the raw milk where he and his family then consumed the milk. This activity continues to this day.

30. Plaintiff Wagoner is also the owner of an internet-based virtual farmers' market known as "Athens Locally Grown." Individuals can become members of Athens Locally Grown ("ALG") by paying an annual membership fee of \$25 per household.

31. Plaintiff Anne Cooper is a member of ALG and resides at 1104 Mill Pointe, Bogart, GA 30622.

32. Plaintiff Wagoner manages and owns ALG, which operates in this fashion:

- (i) Approximately 100 different farms/farmers list their agricultural products with ALG;
- (ii) Some of the 100 different farms/farmers are located in Georgia while some are located in South Carolina;
- (iii) Approximately 2,000 members peruse the ALG list and place orders for the products that are listed there by the 100 farmers;
- (iv) Orders are placed once a week and deliveries are made on Thursdays at a location in Georgia, and this practice continues to this day;

(v) Some of the ALG members, including Plaintiffs Wagoner and Cooper, order raw milk in final package form for personal consumption from three dairies located in South Carolina who list their dairy products with ALG;

(vi) Plaintiff Wagoner drives to South Carolina to pick up the raw dairy products and returns with them to Georgia for distribution to the ALG members and to Plaintiffs Wagoner and Cooper;

(vii) ALG members pay the farmers for the price of the products listed on ALG.

33. On October 15, 2009, Plaintiff Wagoner was driving from South Carolina into Georgia with about 110 gallons of raw milk in final package form. Upon reaching Georgia, Plaintiff Wagoner's truck was searched and seized by officials from Georgia without a warrant. The raw milk in Wagoner's truck was embargoed by officials from Georgia without a warrant.

34. On October 19, 2009, the 110 gallons of raw milk, including milk owned by Plaintiffs Wagoner and Cooper, were destroyed at the order of the Georgia officials and the FDA without a warrant or other legal process.

35. Plaintiff Cooper has an agency relationship with Plaintiff Wagoner, whereby Wagoner, as the agent for Cooper, picks up the raw milk in South Carolina that was legally purchased and is owned by Cooper and delivers that raw milk to Cooper in Georgia.

36. Plaintiff Buck is a member of the Fund and resides at 175 Dairy Lane, Saluda, South Carolina.

37. Plaintiff Buck owns and operates a dairy farm known as Butter Patch Jerseys that is located at 175 Dairy Lane, Saluda, South Carolina. The dairy farm includes approximately 30 dairy cows and a retail store located on the farm.

38. Plaintiff Buck has held a Grade A dairy license from the State of South Carolina since 1987 and has held a retail raw milk license from the State of South Carolina since 2006.

39. It is legal to sell raw milk in South Carolina as long as the seller is either a licensed dairy farm or a licensed retail store.

40. Approximately 25% of the milk produced by Plaintiff Buck's dairy cows is sold in South Carolina as retail raw milk.

41. Plaintiff Buck sells only raw milk and no other raw dairy products, and sells his raw milk on his farm; to a retail store located in Sumter, South Carolina; to a retail store located in Aiken, South Carolina; and to two retail stores located in Columbia, South Carolina.

42. Plaintiff Buck has personal knowledge that people from North Carolina and Georgia, where it is illegal to sell raw milk for human consumption, purchase raw milk at his farm and at the Sumter store, and that people from Georgia purchase raw milk at the Aiken store.

43. Plaintiff Buck has never had any sanctions or penalties levied against his dairy; he has never had to dump even a single load of milk since he has been in business; and, as far as he knows, there has never been any illness caused by the consumption of raw milk produced at his dairy.

44. Defendant Kathleen Sebelius is the current Secretary of the United States Department of Health and Human Services (“HHS”), Defendant Sebelius is being named a party in her official capacity as Secretary of HHS.

45. Defendant HHS is the executive department having jurisdiction over the Food and Drug Administration (“FDA”).

46. Defendant Margaret Hamburg is the current Commissioner of FDA. As Commissioner, Ms. Hamburg is responsible for the direction and supervision of all operations and activities of the FDA. Defendant Hamburg is being named a party in her official capacity as Commissioner of FDA.

47. Defendant FDA is the administrative agency granted authority by Congress to regulate the interstate sale of food in the United States.

48. In a February 21, 2007 letter to Senator Carl Levin, an FDA Acting Deputy Assistant Commissioner for Legislation admitted that “States regulate the intrastate sale of raw milk.”

Jurisdiction and Venue

49. This Court has jurisdiction pursuant to 28 U.S.C. 1331 because this case addresses a federal question and 28 U.S.C. 1346(a)(2) because an agency of the United States is a party.

50. Venue lies with this Court under 28 U.S.C. 1391(e)(2) because this action involves an agency of the United States as a Defendant, because Jennifer Allen resides in this District, and no real property is involved in this action.

Standing

51. The Fund is a nation-wide non-profit organization dedicated to protecting and promoting sustainable, environmentally sound farming practices and direct farm-to-consumer transactions which the Fund believes furthers the common good and general welfare of all Americans. The Fund defends and protects the right of farmers to directly provide, and for consumers to directly obtain, unprocessed and processed farm foods.

52. The Fund and its members are strongly opposed to the enforcement of 1240.61 and 131.110. Many Fund members are, have or will be suffering a deprivation of their constitutional rights from enforcement of 1240.61 and 131.110. Specifically, 1240.61 and 131.110 infringe on the following rights of Fund members: the right to travel across State lines; their right to feed themselves and their families the foods of their choice; their right to raise their families in accordance with their beliefs about food; and their right to have an agent of their choice deliver to them the food of their choice.

53. 1240.61 and 131.110 are beyond Defendant FDA's statutory authority, frustrate the provisions of the domestic laws of no fewer than 28 of the individual States, and are arbitrary and capricious.

54. The FTCLDF is a nation-wide non-profit organization dedicated to protecting and promoting sustainable, environmentally sound farming practices and direct farm-to-consumer transactions which the FTCLDF believes further the common good and general welfare of all Americans. The FTCLDF defends and protects the right of farmers to directly provide, and for consumers to directly obtain, unprocessed and processed farm foods. Toward this end, the FTCLDF provides advocacy, education and legal services for farmers and consumers against any local, State, and federal

government interference with the legal transfer of products produced and processed on the farm.

55. In addition, agrarian-based communities are an integral part of the fabric of American custom and culture and all Plaintiffs help to preserve and protect that culture.

56. All Plaintiffs have chosen to support: the preservation and protection of America's agricultural heritage and traditional farming techniques; the provision and delivery of foods produced thereby directly to the consumer; the maintenance and protection of heirloom varieties of plants and animals constituting a valuable genetic resource which may help to protect America's food supply in the event of a disease outbreak; and the contribution to the national security benefit founded in a diverse and sustainable agricultural system in the event of a terrorist attack or natural disaster that interrupts the distant transportation of centrally-produced food across the country.

57. All of the individual Plaintiffs are, have been, and will be damaged and have suffered, are suffering and will suffer an injury in fact by the prohibitions contained in 1240.61 and 131.110. Specifically, all Plaintiffs are being deprived their fundamental and inalienable rights of (a) traveling across State lines with raw dairy products legally obtained and possessed; (b) providing for the care and well being of themselves and their families, including their children; and (c) producing, obtaining and consuming the foods of choice for themselves and their families, including their children. Plaintiffs are also suffering injury from the promulgation and enforcement of regulations that are beyond the Defendant's authority and that are arbitrary and capricious.

58. The threat of an enforcement action by FDA guarantees standing to the individual Plaintiffs. See *Houston v. Hill*, 482 U.S. 451, 459, n. 7 (1987); *Steffel v. Thompson*, 415 U.S. 452, 459 (1974); *First Nat. Bank of Boston v. Bellotti*, 435 U.S. 765, 785, n. 21 (1978); *Rosenbloom v. Metromedia, Inc.*, 403 U.S. 29, 52-53 (1971); *New York Times Co. v. Sullivan*, 376 U.S. 254, 278 (1964).

59. A declaratory judgment action is the appropriate action to bring when faced with a Hobson's choice, i.e., either comply with a law that is believed to be illegal, or ignore the illegal law and face the possible consequences of noncompliance. See *Abbott Laboratories v. Gardner*, 386 U.S. 136, 152-153, (1967); *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 172 (1967).

60. A favorable ruling on the claims presented in this Complaint would redress Plaintiffs' injury in fact. Specifically, a ruling that 1240.61 and 131.110 are illegal as applied to Plaintiffs would allow the individual Plaintiffs to travel across State lines with legally obtained raw dairy products in their possession; would allow Plaintiffs to provide for the care and well being of themselves and their families, including their children; and would allow Plaintiffs to produce, obtain and consume the foods of their choice.

61. The Fund Plaintiff has standing because several of its members, including but not limited to the individual Plaintiffs, have standing to sue in their own right. The interest at stake in this suit, namely the halting of an intrusive and overly burdensome government agency regulation that interferes with farmers' ability to raise food and consumers' ability to obtain such foods, is germane to the Fund's purpose and mission. None of the claims asserted nor the relief requested require the participation of individual members of the Fund.

Fresh, Unprocessed Raw Milk Does Not Present A Threat To A Person's Health.

62. According to statistics from the Centers for Disease Control, 76 million people become ill each year from consuming contaminated foods.

63. According to CDC statistics for 2007, there were 7,031 reported cases of foodborne outbreaks associated with bacteria, which resulted in 678 hospitalizations and 11 deaths (3 deaths of which were from pasteurized milk).

64. According to those same CDC statistics for 2007, there were only 32 reported cases of illnesses attributed to fresh, unprocessed, raw milk (0.5%); there were only 2 reported hospitalizations attributed to fresh, unprocessed, raw milk (0.3%); and there were no reported deaths attributed to raw milk.

65. According to CDC statistics, 1 out of every 4 people have a foodborne illness every year, yet only 1 out of every 20,000 people who drink fresh, unprocessed, raw milk become sick every year.

66. More people are killed each year from lightning strikes on golf courses than die from milkborne illnesses.

67. As of July 2009, and based on statistics maintained by the Centers for Disease Control on food borne illnesses and outbreaks, the top ten riskiest foods in the United States that are regulated by the FDA include the following: (1) leafy greens; (2) eggs; (3) tuna; (4) oysters; (5) potatoes; (6) cheese (pasteurized); (7) ice cream (pasteurized); (8) tomatoes; (9) sprouts; and (10) berries.

COUNT ONE
1240.61 AND 131.110 EXCEED FDA'S STATUTORY AUTHORITY AND ARE
ARBITRARY AND CAPRICIOUS

68. Paragraphs 1 through 67 are incorporated into this Count as if rewritten herein.

69. 5 U.S.C 702 provides, in part, that “A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.”

70. 5 U.S.C. 706(2) provides, in part, that a Court may “hold unlawful and set aside agency action, findings, and conclusions found to be—
(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
(B) contrary to constitutional right, power, privilege, or immunity;
(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.”

71. 5 U.S.C. 551(13) provides, in part, that “agency action” includes “the whole or a part of an agency rule, . . . relief, or the equivalent or denial thereof, or failure to act.”

72. 5 U.S.C. 551(14) provides, in part, that “rule” means “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. . . .”

73. The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is “the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.” See *Manhattan General Equipment Co. v. Commissioner*, 297 U.S. 129, 134, 56 S.Ct. 397, 400, 80 L.Ed. 528 (1936). See also *Guardians Ass'n v. Civil Service*

Com'n of City of New York, 463 U.S. 582, 615 (1983); *Dixon v. United States*, 381 U.S. 68, 74 (1965).

74. 1240.61 was promulgated pursuant to the Public Health Service Act (“PHSA”) 42 U.S.C. 201 *et seq.*

75. 42 U.S.C. 264 provides, in part, that FDA is authorized to make and enforce regulations that are “necessary to prevent the introduction, transmission, or spread of communicable diseases * * * from one State or possession into any other State or possession.”

76. 21 CFR 1240.3 defines “communicable diseases” as, in part, “Illnesses due to infectious agents or their toxic products.”

77. 1240.61 was promulgated pursuant to Section 264 of the PHSA for the control of communicable diseases, and provides, in part, that “no person shall cause to be delivered into interstate commerce or shall sell or otherwise distribute” any milk or milk product “in final package form for direct human consumption” unless the milk or milk product has first been “pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized.”

78. The way it is written, therefore, 1240.61 makes all raw milk and raw dairy products in final package form that cross state lines, whether or not taken across State lines by a consumer, by an agent of the consumer, or by the producer who legally sells raw milk to a consumer, and which is/are intended for human consumption an “illness” *per se* or a communicable disease *per se*, which is contrary to law.

79. Rather than branding all raw milk and raw dairy products as an “illness” or a “communicable disease,” FDA could use a less stringent means of regulating raw milk and raw dairy products.

80. For example, FDA has a regulation at 21 C.F.R. 101.17 that pertains to unpasteurized juices, and provides, in part, that a warning label on a juice container is an acceptable alternative to pasteurizing the juice, to wit: “WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.”

81. Such a warning label could be used for raw milk and raw dairy products as a less stringent means than an outright ban.

82. With respect to 131.110, the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. 301 *et seq.*, at Section 341 provides, in part, that the FDA may promulgate “standards of identity” and “definitions” for foods in order to “promote honesty and fair dealing in the interest of consumers.”

83. 21 U.S.C. 343(g) provides, in part, that foods for which a standard of identity has been promulgated shall be deemed “misbranded” unless the food “conforms to such definition and standard.”

84. 131.110 provides a definition of “milk” and a standard of identify for “milk.”

85. With respect to the definition of milk, 131.110 defines “milk” as “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.”

86. With respect to the standard of identify for milk, 131.110 provides, in part, that all milk “that is in final package form for beverage use shall have been pasteurized or ultrapasteurized.”

87. The way it is written, therefore, 131.110 makes raw milk and raw dairy products that are in final package form, that cross state lines, and that are intended for human consumption misbranded *per se*, which is contrary to law.

88. Moreover, 131.110 is not consistent with the purposes of the FDCA inasmuch as its effective banning of raw milk is far removed from any reasonable interpretation of the statute's explicit provisions to prevent misbranding or to promote "honesty and fair dealing."

89. When reading 1240.61 and 131.110 together, a citizen who wishes to travel to a neighboring State to legally obtain raw milk and/or raw dairy products (other than exempted raw cheese aged sixty days or more) in final package form, e.g., in a bottle or carton, and take them back into his/her own State for their own personal consumption is prohibited by 1240.61 and 131.110 from doing so unless the milk and/or dairy products have first been pasteurized.

90. Moreover, a farmer who legally sells raw milk and/or raw dairy products (other than exempted raw cheese aged sixty days or more) in their State in final package form, e.g., in a bottle or carton, and sells them to a consumer from another State who then takes them back into his/her own State for their own personal consumption, is prohibited by 1240.61 and 131.110 from doing so unless the milk and/or dairy products have first been pasteurized before being sold to the out-of-State consumer.

91. The FDCA at Section 321(b) defines “interstate commerce” as, in part, “commerce between any State or Territory and any place outside thereof.”

92. Interstate commerce involves goods that are destined for sale in a State other than the place from which they are shipped. See *U.S. v. Food*, 2,998 Cases, 64 F.3d 984, 988 (5th Cir. 1995).

93. In other words, if goods are produced in one State and are destined for sale to an ultimate consumer in another State, those goods enter interstate commerce as soon as they begin their journey outside their state of production. See, e.g., *U.S. v. Food*, 2,998 Cases, 64 F.3d 984, 988 (5th Cir. 1995). See also *Maryland v. Louisiana* 451 U.S. 725, 755 (1981); *Shafer v. Farmers Grain Co.*, 268 U.S. 189, 199- 201 (1925).

94. Although it is legal to *purchase and sell* raw milk in at least 28 States, it is legal to *consume* raw milk in all 50 States.

95. There is nothing in the PHS Act that authorizes FDA to ban the consumption of unpasteurized dairy products that are purchased in a State where such purchase is legal.

96. There is nothing in the PHS Act that authorizes the FDA to find that a product that is legal to sell in more than half the States and where it is legal to consume in all 50 States should be banned as a “communicable disease” or “illness” particularly when there are other foods in the United States that cause more cases of foodborne illness.

97. There is nothing in the FDCA that authorizes FDA to promulgate a “standard of identity” or “definition” for raw milk that requires all milk for human

consumption to first be pasteurized before or after it is taken across State lines lest such milk be deemed “misbranded.”

98. There is nothing in the FDCA that authorizes FDA to prohibit the interstate movement of goods when the goods are purchased by a consumer in one State and then taken across state lines to another State.

99. 1240.61 and 131.110 exceed the scope of authority Congress has delegated to FDA, for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706.

COUNT TWO
1240.61 AND 131.110 VIOLATE THE CONSTITUTIONAL RIGHT TO TRAVEL

100. Paragraphs 1 through 99 are incorporated into this Count as if rewritten herein.

101. The United States Constitution recognizes a fundamental right to travel. *U.S. v. Guest*, 383 U.S. 745 (1966).

102. Any law impacting the right to travel must use the least stringent means possible. *Aptheker v. Secretary of State*, 378 U.S. 500 (1964).

103. Any infringement upon the right to travel must be substantially related to a compelling governmental interest. *Attorney General of New York v. Soto-Lopez*. 476 U.S. 898 (1986).

104. Plaintiffs have a fundamental right to travel from one State to another State in a manner that is free from unnecessary burdens.

105. 1240.61 and 131.110, which effectively ban the interstate movement or distribution of raw milk and raw milk products in final package form for human consumption, are not the least stringent means of regulating the interstate movement or

distribution of raw milk and raw dairy products that are in the possession of people intending to consume them on in the possession of their agents.

106. For example, raw milk and raw dairy products could safely be moved across State lines if the milk and/or dairy product from the originating State was produced in compliance with all laws of the originating State.

107. In addition, the interstate shipment of raw dairy could be addressed through warning labels.

108. Indeed, FDA has a regulation at 21 C.F.R. 101.17 that pertains to unpasteurized juices, and provides, in part, that a warning label on a juice container is an acceptable alternative to pasteurizing the juice, to wit: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

109. Also, Defendants do not have a compelling interest in protecting individuals from traveling across State lines when they have raw milk and/or dairy products in their possession as individuals are capable for themselves in choosing which foods to eat and do not need to be treated as a ward by their government.

110. As a result, 1240.61 and 131.110 are unconstitutional as applied against Plaintiffs.

111. Therefore, 1240.61 and 131.110 constitute a violation of Plaintiffs' fundamental right to travel for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706.

COUNT THREE

1240.61 AND 131.110 VIOLATE THE CONSTITUTIONAL RIGHT TO PRIVACY

112. Paragraphs 1 through 111 are incorporated into this Count as if rewritten herein.

113. The United States Constitution recognizes a fundamental right to privacy. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

114. The fundamental right to privacy is protected by the Due Process clause of the Fifth Amendment to the United States Constitution. See, e.g., *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

115. The fundamental right to privacy includes the fundamental right to raise one's family and be responsible for the care and custody of one's children. *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Stanley v. Illinois* 405 U.S. 645, 649 (1972); *Troxel v. Granville*, 530 U.S. 57, 65 (2000).

116. The right to privacy also includes the fundamental right to be free from governmental interference with one's bodily and physical health. *Rochin v. California*, 342 U.S. 165 (1952); *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992).

117. Plaintiffs have a fundamental right to raise their family in their own way, which includes what foods they do and do not choose to consume for themselves and their families.

118. Plaintiffs have a fundamental right to their own bodily and physical health, which includes what foods they do and do not choose to consume for themselves and their families.

119. As a result, 1240.61 and 131.110 violate Plaintiffs' fundamental privacy rights of raising their families in the way they see fit and in providing them and their families with the foods of their own choice.

120. Therefore, 1240.61 and 131.110 constitute a violation of Plaintiffs' substantive due process privacy right of raising their families in the way they see fit and in providing them and their families with the foods of their own choice, for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706.

COUNT FOUR
1240.61 AND 131.110 VIOLATE THE NON-DELEGATION DOCTRINE

121. Paragraphs 1 through 120 are incorporated into this Count as if rewritten herein.

122. Article 1, Section 1 of the United States Constitution provides, in part, that "All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives."

123. Only Congress, not the executive, can pass laws that restrict personal liberty. *Zemel v. Rusk*, 381 U.S. 1, 85 S.Ct. 1271 (1965) (dissent); *Panama Refining Co. v. Ryan*, 293 U.S. 388, 55 S.Ct. 241 (1935); *Whitman v. American Trucking Associations*, 531 U. S. 457, 121 S.Ct. 903 (2001).

124. The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is "the power to adopt regulations to carry into effect the will of Congress as expressed by the statute." See *Manhattan General Equipment Co. v. Commissioner*, 297 U.S. 129, 134, 56 S.Ct. 397, 400, 80 L.Ed. 528 (1936). See also *Guardians Ass'n v. Civil Service*

Com'n of City of New York, 463 U.S. 582, 615 (1983); *Dixon v. United States*, 381 U.S. 68, 74 (1965).

125. Although it is legal to *purchase and sell* raw milk in at least 28 states, it is legal to *consume* raw milk in all 50 states.

126. There is nothing in the PHSa that authorizes FDA to ban the consumption of unpasteurized dairy products that are purchased in a State where such purchase is legal.

127. There is nothing in the PHSa that authorizes the FDA to find that a product that is legal to sell in more than half the States and is legal to consume in all 50 States should be banned as a “communicable disease” or “illness” particularly when there are other foods in the United States that cause more instances and greater severity of foodborne illness.

128. There is nothing in the FDCA that authorizes FDA to promulgate a “standard of identity” or “definition” for raw milk that requires all milk for human consumption to first be pasteurized before or after it is taken across State lines lest such milk be deemed “misbranded.”

129. There is nothing in the FDCA that authorizes FDA to prohibit the interstate movement of goods when the goods are legally purchased by a consumer in one State and then taken across state lines to another State.

130. As a result, 1240.61 and 131.110 violate the separation of powers/non-delegation doctrine because only Congress, not the FDA, has the authority to enact legislation that restricts the personal liberty of persons who wish to consume raw milk and raw dairy products by traveling into another State to obtain those products.

131. Therefore, 1240.61 and 131.110 constitute a violation of the non-delegation doctrine, recognized by Article 1, Section 1 of the United States Constitution, for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706.

COUNT FIVE
1240.61 AND 131.110 VIOLATE SUBSTANTIVE DUE PROCESS

132. Paragraphs 1 through 131 are incorporated into this Count as if rewritten herein.

133. The Fifth Amendment to the United States Constitution provides, in part, that “no person shall be * * * deprived of life, liberty, or property, without due process of law.”

134. In order to comport with substantive due process, laws must bear a “reasonable relation to a proper legislative purpose, and [must be] neither arbitrary nor discriminatory.” See *U.S. v. Buckner*, 894 F.2d 975, 978 (8th Cir. 1990).

135. Contract rights are a form of property. See *U.S. Trust Co. of New York v. New Jersey*, 431 U.S. 1 (1977).

136. Government’s police power is limited when it attempts to transgress fundamental rights. See *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415-416 (1922).

137. Plaintiff Wagoner has an agency relationship with Plaintiff Cooper whereby Wagoner drives to South Carolina and picks up the raw milk in final package form that is legally obtained, paid for and owned by Plaintiff Cooper.

138. Plaintiff Wagoner drives from South Carolina across state lines into the State of Georgia to deliver the raw milk to Plaintiff Cooper, who then consumes it in Georgia.

139. If Plaintiff Cooper has liberty interests, i.e., right to travel and right to privacy, to drive into South Carolina and legally purchase, obtain and possess raw milk in final package form for her consumption, then it is irrational to prevent Cooper from using the services of an agent for that same purpose.

140. Moreover, raw milk in final package form that is legally obtained in South Carolina by Cooper is no safer than raw milk in final package form that is obtained in South Carolina by Cooper's agent. Likewise, raw milk in final package form that is obtained in South Carolina by Wagoner, Cooper's agent, is no less safe than if that same milk was picked up by Cooper herself.

141. In addition, milk that is in final package form which is sold by Plaintiff Buck in South Carolina, where it is legal to sell raw milk, should not serve as a basis for imposing liability on Buck when that milk is purchased by a resident from another State and then taken back by that out-of-State resident to their State of residence.

142. As a result, 1240.61 and 131.110 present no legitimate federal interest in preventing Plaintiff Cooper from receiving raw milk and dairy products from her agent or in preventing Plaintiff Buck from legally selling raw milk in final package form in his State where it is legal to do so.

143. Also, 1240.61 and 131.110 do not present any legitimate federal interest in prohibiting raw milk from being transported across State lines by an agent, when those products were legally purchased in accordance with State law and when they

have enlisted the services of an agent to have their own goods delivered to them by their own agent, or by a consumer who legally purchases raw milk in a State where it is legal to do so from a producer such as Plaintiff Buck.

144. Therefore, 1240.61 and 131.110, by irrationally restricting the use of an agent to accomplish what the principal herself ought to be free to do, or by restricting the legal sale of raw milk across in a State from a producer to an out-of-State consumer who takes that milk back to the out-of-State person's State of residence, constitute a violation of substantive due process of the Fifth Amendment to the Constitution of the United States, for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

- A. A declaration that 21 CFR. 1240.61 and 21 CFR 131.110 violate the fundamental right to travel;
- B. A declaration that 21 CFR 1240.61 and 21 CFR 131.110 violate the fundamental right to privacy;
- C. A declaration that 21 CFR 1240.61 and 21 CFR 131.110 violate the substantive due process clause of the Fifth Amendment;
- D. A declaration that 21 CFR 1240.61 and 21 CFR 131.110 violate Article 1, Section 1 of the United States Constitution;
- E. A declaration that 21 CFR 1240.61 and 21 CFR 131.110 are arbitrary and capricious and exceed the statutory authority Congress has delegated to FDA in violation of 5 U.S.C. 706(2)(A) and (2)(C);

- F. A declaration that 21 CFR 1240.61 and 21 CFR 131.110 violate the separation of powers or, in the alternative, non-delegation doctrines;
- G. An injunction enjoining any further enforcement, civil, criminal, administrative or otherwise, of 21 CFR 1240.61 and 21 CFR 131.110 against Plaintiffs or anyone else who wishes to distribute or take across State lines raw milk and/or raw dairy products in final package form for personal consumption;
- H. An injunction enjoining Defendants from spending or receiving federal, State or local taxpayer Funds on any activity related to enforcement of 21 CFR 1240.61 and 21 CFR 131.110;
- I. Pursuant to applicable federal law, award to Plaintiffs all of their attorneys fees incurred in this matter;
- J. Pursuant to applicable federal law, award to Plaintiffs all of the costs they have incurred in this matter;
- K. Award to Plaintiffs all other relief as applicable that the Court deems just and reasonable.

Dated: February 18, 2010

Respectfully submitted,

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