IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

Farm-to-Consumer Legal Defense Fund, et al.	:	**Case No. 5:10-cv-4018**
Plaintiffs	:	**Judge Mark W. Bennett**
v.	:	
Sebelius, et al.	:	
Defendants	:	

PLAINTIFFS' BRIEF IN SUPPORT OF RESISTANCE TO DEFENDANT'S REVISED MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

"It is dangerous to be right when the government is wrong."-Voltaire

This case is about two administrative regulations that were adopted by Defendants pursuant to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. 301, *et seq*., and the Public Health Service Act ("PHSA"), 42 U.S.C. 201, *et seq*. The first regulation, 21 C.F.R. 131.110 ("131.110"), requires that all "milk" that is in "final package form for beverage use" has to be "pasteurized" and if it is not pasteurized then it is deemed "misbranded."[1] The other regulation, 21 C.F.R. 1240.61 ("1240.61"), provides that all milk in interstate commerce "in final package form" has to be pasteurized before it can cross state lines.

Plaintiffs are consumers of raw milk, a farmer who sells raw milk, and a non-profit organization some of whose members are Plaintiffs in this action. Plaintiffs brought a declaratory judgment action seeking, in part, declarations that 1240.61 and 131.110 (hereinafter "the regulations") are illegal as applied to Plaintiffs' conduct. Defendants filed a motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim.

[1] *See* 21 U.S.C. 343(g).

The Court denied Defendants' motion to dismiss for lack of subject matter jurisdiction. Defendants' motion to dismiss for failure to state a claim was not ruled on by the Court. Following its denial of Defendants' motion, the Court referred three questions *ante* to the FDA asking FDA clarify its position on how it interpreted and applied the regulations to Plaintiffs' conduct. FDA answered those questions *ante* and stated that all Plaintiffs are violating both 1240.61 and 131.110. Defendants have now renewed their motion to dismiss for failure to state a claim and they make the same basic arguments, all of which lack merit as explained below.

In addition, Defendants have filed a summary judgment motion and raise one new argument, that of statute of limitations. As explained below, that argument also lacks merit. Also, most of Defendants' summary judgment motion deals with an administrative record that is almost 25 years old and with how 1240.61 and 131.110 were adopted pursuant to that archaic administrative record. However, the administrative record in this case and the basis for adopting 1240.61 and 131.110 have nothing to do with Plaintiffs' claims in this case. Again, Plaintiffs are making purely legal claims in this case and seek declarations accordingly.

Consequently, and as described in more detail below, Defendants' motion for summary judgment is not well taken and it should be denied.

STATEMENT OF FACTS

Plaintiffs' response to Defendants' statement of material facts is incorporated by reference as if rewritten herein. Plaintiffs' statement of additional material facts is also incorporated by reference as if rewritten herein.

ARGUMENT

I. Standard of Review.

As this Court recently stated in the case of *McGraw v. Wachovia Securities, L.L.C.*, 756 F. Supp. 1053 (N.D. Iowa 2010) (J. Bennett):

> Motions for summary judgment essentially "define disputed facts and issues and ... dispose of unmeritorious claims [or defenses]." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 127 S.Ct. 1955, 1982, 167 L.Ed.2d 929 (2007); *see Celotex Corp. v. Catrett,* 477 U.S. 317, 323–24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) ("One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses...."). Summary judgment is only appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no *genuine* issue of *material* fact and that the moving party is entitled to a judgment as a matter of law." *Id.* 56(c) (emphasis added); *see Woods v. DaimlerChrysler Corp.,* 409 F.3d 984, 990 (8th Cir.2005) ("Summary judgment is appropriate if viewing the record in the light most favorable to the nonmoving party, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law.").
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> A fact is *material* when it " 'might affect the outcome of the suit under the governing law.' " *Johnson v. Crooks,* 326 F.3d 995, 1005 (8th Cir.2003) (quoting *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)). Thus, "the substantive law will identify which facts are material." *Anderson,* 477 U.S. at 248, 106 S.Ct. 2505. An issue of material fact is *genuine* if it has a real basis in the record, *Hartnagel v. Norman,* 953 F.2d 394, 395 (8th Cir.1992) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586–87, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986)), or when " 'a reasonable jury could return a verdict for the nonmoving party' on the question," *Woods,* 409 F.3d at 990 (quoting *Anderson,* 477 U.S. at 248, 106 S.Ct. 2505); *see Diesel Machinery, Inc. v. B.R. Lee Indus., Inc.,* 418 F.3d 820, 832 (8th Cir.2005) (stating genuineness depends on "whether a reasonable jury could return a verdict for the nonmoving party based on the evidence").
>
> The moving party bears "the initial responsibility of informing the district court of the basis for its motion and identifying those portions of the record which show a lack of a genuine issue," *Hartnagel,* 953 F.2d at 395 (citing *Celotex,* 477 U.S. at 323, 106 S.Ct. 2548), and demonstrating that it is entitled to judgment according to law. *See Celotex,* 477 U.S. at 323, 106 S.Ct. 2548 ("[T]he motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the

> entry of summary judgment, as set forth in Rule 56(c), is satisfied."). Once the moving party has successfully carried its burden under Rule 56(c), the nonmoving party has an affirmative burden to go beyond the pleadings and by depositions, affidavits, or otherwise, designate "specific facts showing that there is a genuine issue for trial." FED.R.Civ.P. 56(e); *Mosley v. City of Northwoods, Mo.,* 415 F.3d 908, 910 (8th Cir.2005) ("The nonmoving party may not 'rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial.' " (quoting *Krenik v. County of Le Sueur,* 47 F.3d 953, 957 (8th Cir.1995))).

Id. at 1063-1064.

In this case, the material facts are not in dispute. Although the parties may disagree over whether FDA was actively involved in the embargo and destruction of the milk owned by Plaintiffs Wagoner and Cooper, those facts are not material to any of the Plaintiffs' claims. The material facts are FDA admits that 1240.61 and 131.110 regulates Plaintiffs' conduct and FDA believes that Plaintiffs' conduct constitutes a violation of law. Plaintiffs dispute these assertions of FDA.

Because Defendants are not entitled to judgment as a matter of law, their motion for summary judgment is not well taken and it should be denied.

II. Plaintiffs' substantive challenge to 1240.61 and 131.110 are not precluded by the six year statute of limitations of 28 U.S.C. 2401.

FDA argues that Plaintiffs' claims are barred by the six-year statute of limitations contained at 28 U.S.C. 2401. However, that argument fails for four reasons: (1) Plaintiffs' claims accrue each time they engage in the conduct described in the complaint; (2) a challenge to the substantive (not procedural) validity of an administrative regulation can be brought at any time; (3) an as applied challenge to an administrative regulation can be brought within six years from the date the challenger first has a claim against the agency; and (4) a continuing violation of the rule tolls the statute of limitations. As

explained below, Plaintiffs' claims are not time barred.

A cause of action against an administrative agency first accrues for purposes of 28 U.S.C. 2401 as soon as, but not before, the person challenging the agency action can institute and maintain a suit in court. *See Spannaus v. U.S. Dept. of Justice*, 824 F2d 52, 56 (D.C. Cir. 1987). As stated by the United States Supreme Court, 28 U.S.C. 2401 bars a civil suit against the United States "if the right to bring it first accrued more than six years prior to the date of filing the suit." *Crown Coat Front Co. v. U.S.* 386 U.S. 503, 510, 87 S.Ct. 1177, 1181 (1967). As the Eighth Circuit has stated, a plaintiff's claim "accrues for purposes of § 2401(a) when the plaintiff 'either knew, or in the exercise of reasonable diligence should have known, that [he or she] had a claim.'" *Izaak Walton League of America, Inc. v. Kimbell*, 588 F.3d 751, 759 (8th Cir. 2009) (citation omitted). In other words, the claim first accrues "on the date when all the events have occurred which fix the liability of the Government and entitle the claimant to institute an action." *Chandler v. U.S. Air Force,* 255 F.3d 919, 921 (8th Cir. 2001) (citation omitted). *See also Schoeffler v. Kempthorne*, 493 F.Supp.2d 805, 815 (W.D. La. 2007) ("In the Fifth Circuit, the general rule is that a cause of action emerges when the alleged wrong occurs."). In a regulatory context, therefore, a claim against an administrative regulation does not accrue until the challenger first becomes subject to the requirements of the regulation.

Moreover, there are two types of challenges to an administrative regulation, a procedural challenge and a substantive challenge. When the substantive (not procedural) validity of an administrative regulation is being challenged, the statute of limitations that would ordinarily apply is not applicable. *See, e.g., Tri-State Motor Transit Co. v. I.C.C.*,

739 F.2d 1373, 1375, fn. 2 (8th Cir. 1984). ("However, we hold that the Hobbs Act does not bar judicial review on the substantive validity of the rule, even if more than sixty days have elapsed since its issuance."). Thus, when an individual claims that an administrative regulation "of continuing application" has been promulgated by an agency in "excess of its statutory authority," the regulation "may be challenged after a limitations period has expired." *Wind River Min. Corp. v. U.S.*, 946 F.2d 710, 714-715 (9th Cir. 1991) ("If, however, a challenger contests the substance of an agency decision as exceeding constitutional or statutory authority, the challenger may do so later than six years following the decision by filing a complaint for review of the adverse application of the decision to the particular challenger. Such challenges, by their nature, will often require a more 'interested' person than generally will be found in the public at large."). *See also Public Citizen v. Nuclear Regulatory Com'n*, 901 F.2d 147, 152-153 (D.C. Cir. 1990) ("[A]lthough a statutory review period permanently limits the time within which a petitioner may claim that an agency action was *procedurally* defective, a claim that agency action *was violative of statute* may be raised outside a statutory limitations period…") (emphasis added).

Substantive challenges to an administrative regulation are allowed at any time because "administrative rules and regulations are capable of continuing application" and thus limiting "the right of review of the underlying rule would effectively deny many parties ultimately affected by a rule an opportunity to question its validity." *Functional Music, Inc. v. F.C.C.*, 274 F.2d 543, 546 (D.C. Cir. 1959). To otherwise prohibit judicial review of the applicability of an ongoing administrative regulation would allow the promulgating agency to engage in a potentially *ultra vires* act. *See Natural Resources*

Defense Council, Inc. v. Evans, 232 F.Supp.2d 1003, 1024 (N.D. Cal. 2002) ("The government should not be permitted to avoid all challenges to its actions, even if *ultra vires,* simply because the agency took the action long before anyone discovered the true state of affairs....").

Indeed, when Congress was considering an amendment to the FDCA, a debate arose over whether the Act was meant to reduce, restrict or limit judicial review of actions of the FDA which were alleged to be in excess of FDA's statutory authority. In a memo submitted to Congress by the Department of Justice during Congressional debate, DOJ admitted that when an agency has exceeded its authority, judicial review should *always* be available: "As a matter of fact, the entire subsection is really unnecessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 143, 87 S.Ct. 1507, 1512 (1967), *revd* on other grounds. Thus, the United States Supreme Court ruled that the FDCA's "legislative history shows rather conclusively that the specific review provisions were designed to give an additional remedy and not to cut down more traditional channels of review." *Id*. at 142. Consequently, 28 U.S.C. 2401 does not foreclose a declaratory judgment action seeking a pre-enforcement challenge to the substantive validity of FDA regulations whose applicability has already been determined.

In addition, an as applied (not a facial) challenge to an administrative regulation is not foreclosed by the six-year statute of limitations of 28 U.S.C. 2401. When an

individual challenges "the substance of an agency decision as exceeding constitutional or statutory authority, the challenger may do so later than six years follow (sic) the decision by filing a complaint for review of the adverse *application* of the decision *to the particular challenger*...." *Natural Resources Defense Council, Inc. v. Evans,* 232 F.Supp.2d 1003, 1024 (N.D. Cal. 2002) (emphasis added). *See also Commonwealth Edison Co. v. U.S. Nuclear Regulatory Com'n*, 830 F.2d 610, 614 (7th Cir. 1987) ("Allowing review when a challenge is brought to the application of a rule is in keeping with the rule of *Abbott Laboratories* that suggests that the provision for direct review of legislative rules should not, without more, serve to prohibit indirect review of those rules in enforcement proceedings."); *Utu Utu Gwaitu Paiute Tribe of Benton Paiute Reservation v. Department of Interior*, 766 F.Supp. 842, 846 (E.D. Cal. 1991) ("Unlike a procedural irregularity, which will have occurred by the time the regulation is published as "final" in the Federal Register, unlawful agency interpretation of a regulation is not apparent, unless the regulation is clearly subject to facial attack, *until it has been applied*.") (emphasis added); *State of Tex. v. U.S.*, 730 F.2d 409, 415 (5th Cir. 1984) ("When an agency applies a previously adopted rule in a particular case, the Hobbs Act does not bar judicial review of the substance of the rule, even if more than sixty days have elapsed since its issuance."). Thus, when an administrative regulation "sets a standard of conduct for all to whom its terms apply" and operates as a standard of conduct "upon any particular individual," the regulation may be "appropriately the subject of [an] attack…." *Columbia Broadcasting System v. U.S.*, 316 U.S. 407, 418-419, 62 S.Ct. 1194 (1942).

In other words, regulations that were promulgated in 1973 and 1987 are subject to

challenge in 2009 and later[2] when subsequent generations of individuals, because of their recent conduct, become subject to the proscriptions of the rule and thus have an opportunity to present their challenges to the substantive legality of the rules. Thus, 28 U.S.C. 2401 does not foreclose a declaratory judgment action seeking a pre-enforcement challenge to the application of regulations whose applicability has already been determined by FDA.

Finally, the strictures of 28 U.S.C. 2401 can be tolled if there exists a "continuing violation." *See, e.g., Bunda v. Potter*, 369 F.Supp.2d 1039, 1053 (N.D. Iowa 2005) (J. Bennett) ("Therefore, those parts of the Postmaster's motion for summary judgment on Bunda's hostile environment claim asserting that Bunda failed to exhaust her administrative remedies, and failed to establish a 'continuing violation,' as to the 1999 incidents of harassment will also be denied."). In the "hostile work environment" context, a continuing violation occurs if "the acts before and after the limitations period were so similar in nature, frequency, and severity that they must be considered to be part and parcel of the hostile work environment that constituted the unlawful employment practice that gave rise to this action." *Rowe v. Hussmann Corp*., 381 F.3d 775, 781 (8th Cir. 2004). *Cf. Morris v. Conagra Foods, Inc*., 435 F.Supp.2d 887, 904 (N.D. Iowa 2005) (J. Bennett) ("In sum, Morris's assertions consist of nothing more than an amalgamation of discrete, isolated instances of misconduct."). Thus, a declaratory judgment action seeking a pre-enforcement challenge to the application of FDA regulations whose applicability has already been determined should toll the limitation of 28 U.S.C. 2401 if each of the alleged "illegal" acts are similar in nature and are ongoing

[2] Plaintiffs are alleging they have been taking raw milk across state lines since at least January 2009 to the present. *See* Appendix, pgs 1-38.

or continuous.

In this case, Plaintiffs could not have challenged the validity of 1240.61 and 131.110 unless and until they become subject to them, i.e., until they engaged in the alleged "illegal" conduct proscribed by the rules. Once they became subject to the proscriptions of 1240.61 and 131.110, Plaintiffs could then challenge them. As it is, Plaintiffs allege they have engaged in a continuous pattern of "illegal" conduct only as recently as 2009. Since the complaint was filed only a year later in 2010, 28 U.S.C. 2401 does not bar Plaintiffs' claims.

Moreover, Plaintiffs are arguing that 1240.61 and 131.110 exceed the statutory authority of FDA delegated to it by the FDCA. Specifically, 1240.61 and 131.110 suggest that (1) Plaintiffs are engaged in interstate commerce and FDA can dictate to consumers what type of dairy product they can and cannot purchase in interstate commerce, (2) Plaintiffs' raw milk and/or raw dairy products constitute a "communicable disease" *per se*, and (3) they promote the "honesty and fair dealing"[3] mandates of the FDCA when in fact these regulations do not promote honesty and fair dealing. As such, these rules exceed the authority delegated to FDA by Congress. Therefore, Plaintiffs' substantive, as applied challenge to the rules cannot be time barred.

In addition, Plaintiffs are claiming that even if FDA has the authority to categorize raw milk and raw dairy products as a "communicable disease," Plaintiffs' constitutional right to travel and right to privacy are being violated by FDA's application of 1240.61 and 131.110 against them. Consequently, the proscription of 28 U.S.C. 2401 cannot prevent their as applied constitutional challenge. Finally, because Plaintiffs are

[3] *See* 21 U.S.C. 341.

engaged in an ongoing and continuous course of "illegal" conduct, the proscriptions of 28 U.S.C. 2401 are tolled as long as Plaintiffs engage in their conduct.

FDA, however, makes the unique argument that Plaintiffs should have filed their claims six years after 1240.61 and 131.110 were promulgated. That argument lacks merit as the cases cited above demonstrate. Moreover, that argument is based on the supposition that Plaintiffs are making a procedural challenge to the rules, which Plaintiffs are not; Plaintiffs' claims are substantive in nature.

FDA also argues that Plaintiffs are making a "facial" challenge to 1240.61 and 131.110 but that is erroneous. Plaintiffs are challenging FDA's underlying legal authority to issue the rules as they are currently written, i.e., FDA does not have the authority to (1) compel a consumer to purchase and consume a specific agricultural product (pasteurized milk) at the expense of another (raw milk), (2) classify Plaintiffs' raw milk as a communicable disease *per se*, or (3) disguise a prohibition on the sale of an otherwise legal dairy product as a "standard of identity." As explained above, Plaintiffs' case constitutes a substantive challenge to FDA's underlying authority to issue these rules in this format in the first place, and thus 1240.61 and 131.110 can be challenged at any time.

FDA at no time cites to any case that holds the proscriptions of 28 U.S.C 2401 apply to a declaratory judgment action. Rather, all that is required to bring a declaratory judgment action is an independent basis of jurisdiction. *See, e.g., Oeltjenbrun v. CSA Investors, Inc.*, 3 F.Supp.2d 1024, 1033 (N.D. Iowa 1998) (J. Bennett) ("The federal Declaratory Judgment Act 'is a procedural statute, not a jurisdictional statute.' [citation omitted]. Therefore, there must be some basis for federal jurisdiction other than the

Declaratory Judgment Act. [citation omitted]. The basis for federal jurisdiction over the Declaratory Judgment Act claim here is federal question jurisdiction, 28 U.S.C. § 1331, based on an alleged violation of the CEA."). In this case, Plaintiffs' claims present federal questions and are based on the federal APA, the constitutional right to travel, the constitutional right of privacy, substantive due process, the non-delegation doctrine under Article 1 Section 1, and Congress' intent when it delegated authority to the FDA to implement the FDCA. Consequently, 28 U.S.C. 2401 cannot bar Plaintiffs' claims.

For these reasons, Defendants' renewed motion to dismiss/summary judgment on the issue of statute of limitations is not well taken and it should be denied.

III. FDA's interpretation and application of 1240.61 and 131.110 against Plaintiffs' conduct is arbitrary, capricious, contrary to constitutional right, and in excess of statutory authority.

7 U.S.C. 706(2) provides, in part, that agency action is unlawful if it is "(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." *See also B&D Land and Livestock Co. v. Schafer*, 584 F. Supp.2d 1182, 1190 (N.D. Iowa 2008) (J. Bennett). To be reviewable, however, agency action must be "final," which means, first, that "the action must mark the 'consummation' of the agency's decisionmaking process" (citation omitted) and, second, the action "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow' (citation omitted)…." *Bennett v. Spear*, 520 U.S. 154, 177-178, 117 S.Ct. 1154 (1997). *See also In re Sac & Fox Tribe of Mississippi in Iowa/Meskwaki Casino Litigation*, 340 F.3d 749, 756 (8th Cir. 2003).

Final agency action is arbitrary when, in part, the agency's decision evinces "a clear error of judgment." *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285, 95 S.Ct. 438 (1974). *See also South Dakota v. Ubbelohde*, 330 F.3d 1014, 1031 (8th Cir. 2003); *B & D Land and Livestock Co. v. Veneman*, 332 F.Supp. 2d 1200, 1209 (N.D. Iowa 2004) (J. Bennett). Final agency action is in excess of statutory authority when it does not "give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843, 104 S.Ct. 2778 (1984). Final agency action that is contrary to constitutional right is unlawful unless it promotes a compelling public interest. *See Shapiro v. Thompson*, 394 U.S. 618, 634 (1969) ("[a]ny classification which serves to penalize the exercise of [a constitutional] right, unless shown to be necessary to promote a compelling governmental interest, is unconstitutional."). Because it is the duty of a court to construe a statute, courts must "reject administrative constructions which are contrary to clear congressional intent." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. at 843, fn. 9. *See also Baptist Health v. Thompson*, 458 F.3d 768, 774 (8th Cir. 2006); *Garrelts v. SmithKline Beecham Corp*., 943 F.Supp. 1023, 1040, fn. 15 (N.D. Iowa 1996) (J. Bennett).

If ever there was any doubt about FDA's interpretation and application of 1240.61 and 131.110 to Plaintiffs' conduct prior to the time the complaint in this matter was filed, all doubt has now been removed by FDA's answering of the Court's questions *ante*. *See* Doc. #43-1. In answering the Court's questions, FDA has now clearly stated that all Plaintiffs are violating 1240.61 and 131.110 when they engage in the conduct described in the complaint. Consequently, Plaintiffs' challenge to the applicability of these

regulations to their conduct is ripe for summary judgment.

As explained below, none of the Plaintiffs in this case are engaged in "interstate commerce" and Plaintiffs cannot be told that if they purchase a dairy product it must be pasteurized. Moreover, Plaintiffs' raw milk *per se* cannot constitute a "communicable disease." Finally, 1240.61 and 131.110 do not promote "honesty and fair dealing" as required under the FDCA. In addition, FDA has illegally prohibited what Congress has expressly decided *not* to prohibit, and 1240.61 and 131.110 are not rationally related to any legitimate governmental interest. Consequently, FDA's interpretation of 21 C.F.R. 1240.61 and 131.110 as applied against Plaintiffs' conduct is arbitrary and capricious, is not in accordance with applicable law, is contrary to constitutional right, and exceeds its statutory authority under the FDCA.

Therefore, FDA's motion for summary judgment is not well taken and it should be denied.

A. Plaintiffs are not engaged in interstate commerce.

21 U.S.C. 321(b) defines "interstate commerce" as "commerce between any State or territory and any place outside thereof." Courts have interpreted the purpose behind the FDCA's interstate commerce regulatory program to be to "safeguard the consumer from the time the food is introduced into the channels of interstate commerce to the point that it is delivered to the ultimate consumer." *United States v. Wiesenfeld Warehouse Co.,* 376 U.S. 86, 92, 84 S.Ct. 559, 11 L.Ed.2d 536 (1964). In other words, the various sections of the FDCA are "elements of an overall scheme designed to regulate the interstate flow of goods from the moment of their introduction into interstate commerce until the moment of their delivery to the ultimate consumer." *United States v. Sullivan*,

332 U.S. 689, 696, 68 S.Ct. 331, 92 L.Ed. 297 (1948). As this very Court has recognized, nothing in FDA's regulations at 21 C.F.R. Part 1240 "broadens or narrows the 'interstate commerce' language used in § 1240.61 beyond the scope of the statutory 'interstate commerce' provisions." *Farm-to-Consumer Legal Defense Fund v. Sebelius*, 734 F.Supp.2d 668, 688, fn. 5 (N.D. Iowa 2010) (J. Bennett).

The Eighth Circuit has recognized the distinction between inter-state sales and intra-state sales. In the case of *Impro Products, Inc. v. Herrick*, 715 F.2d 1267, 1269 (8th Cir. 1983), the Eighth Circuit stated that the FDCA applies to "drugs marketed in interstate commerce, and to those marketed in intrastate commerce *which contain components that have been shipped interstate*." *Id*. at 1269 (emphasis added). In other words, if a drug contained an ingredient whereby the ingredient itself was shipped and received in interstate commerce, then the *intrastate* sale of that drug would be subject to FDA's jurisdiction under the FDCA. In this case, however, there are no out-of-state ingredients in the milk that is being purchased by the Plaintiffs.[4] All of the milk being purchased by Plaintiffs is produced in the state of purchase; thus, all of the sales of the milk are *intrastate* and are beyond the jurisdiction of the FDCA and FDA.

In addition, the Eighth Circuit has also analyzed "interstate commerce" in the context of the interstate transport and receipt of stolen handguns. In *U.S. v. Ruffin*, 490 F.2d 557, 560 (8th Cir. 1974), the issue was whether the possession by Missouri residents of handguns that had been stolen from Illinois 7 months and 41 days previously meant that the individuals had received the handguns in "interstate commerce." The *Ruffin*

[4] In the case of the farmer Plaintiff, Michael Buck, his affidavit demonstrates that all of the cows he milks are born and raised in South Carolina, and all of the jugs and labels he obtains are from vendors located in South Carolina. *See* Appendix, pg. 6. Thus, the milk sold by Buck is an *intrastate* sale only.

court held that no, interstate commerce was not involved because the government did not make any showing that the Missouri residents received the handguns in interstate commerce. " [F]or the receipt to be cognizable the government must show that at the time the gun was received it was part of an interstate transportation." *Id*. at 560.

Again, in this case, the raw milk is not being transported across state lines before it is sold. Only after the milk is sold is it taken across state lines, thus, it constitutes an intrastate sale that is not subject to the jurisdiction of the FDCA or the FDA. Indeed, and as the Court recognized during oral argument on July 22, 2010, FDA's interpretation of 1240.61 and 131.110 would literally mean that a 3,500 gallon stainless steel milk truck containing 3,500 gallons of raw milk that crosses state lines would not be considered in "interstate commerce" because the raw milk in the stainless steel truck is not in "final package form." Such a truck could, therefore, distribute in interstate commerce the raw milk for human consumption. Consequently, FDA's application of the raw milk ban to Plaintiffs' conduct in this case is not rational and Plaintiffs' should not be regarded as engaging in interstate commerce.

Plaintiffs recognize that the FDCA "rests upon the constitutional power resident in Congress to regulate interstate commerce." *United States v. Walsh,* 331 U.S. 432, 434, 67 S.Ct. 1283, 91 L.Ed. 1585 (1947). Plaintiffs also recognize that under the Commerce Clause, Congress can regulate the *intrastate* sale of goods if those intrastate sales impact "interstate commerce." *See, e.g., Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 85 S.Ct. 348, 13 L.Ed.2d 258 (1964); *Wickard v. Filburn*, 317 U.S. 111, 63 S.Ct. 82, 87 L.Ed. 122 (1942); *Gibbons v. Ogden*, 9 Wheat. 1, 6 L.Ed. 23 (1824). However, Congress has chosen *not* to preempt the States under the FDCA or regulate the intrastate

sales of raw dairy products and has instead left that decision to the several States. *See Borden Co. v. Liddy*, 200 F. Supp. 221, 226 (S.D. Iowa 1961) ("Borden's contention that the federal government has pre-empted the field by establishing a minimum standard for ice cream cannot be sustained."). Indeed, as the FDA admits, "21 C.F.R. 1240.61 does not apply to purely intrastate sales of raw milk." *See* Appendix, pg. 43. Thus, neither the FDCA nor 1240.61 governs the intrastate sales nature of Plaintiffs' conduct.

It follows that the FDCA does not encompass the intrastate sale of goods that are sold in one state to a consumer who then takes those goods back to another state. In other words, when Plaintiffs go to one state, purchase raw dairy products in that state, and then take those products back to their own state of residence, that conduct does not constitute "interstate commerce" as defined in the FDCA at 21 U.S.C. 321(b). This is so because once Plaintiffs engage in the intra-state purchase of the raw dairy product, they are already protected from the vagaries that may happen when the product is commercially transported in interstate commerce. *See United States v. Wiesenfeld Warehouse Co.,* 376 U.S. 86, 92, 84 S.Ct. 559, 11 L.Ed.2d 536 (1964); *United States v. Sullivan*, 332 U.S. 689, 696, 68 S.Ct. 331, 92 L.Ed. 297 (1948).

Therefore, in the absence of a legislative change to the FDCA, interstate commerce under the FDCA does not involve the situation where an individual travels to one state, makes a purchase of goods, and then takes those goods back to the individual's state of residence. That conduct is clearly an intrastate sale. Thus, Plaintiffs' conduct does not constitute "interstate commerce" as contemplated by the FDCA.

FDA, however, argues in its answers to the Court's questions *ante* that Plaintiffs are engaged in interstate commerce. *See* Doc. #43-1, Appendix, pgs. 46-48. FDA

supports its argument with citations to several cases. However, those cases are not on point.

For example, the *Bruhn's Freezer Meats* and *Simpson* cases did not even involve the FDCA. *Bruhn's Freezer Meats* involved the Packer's and Stockyard Act that specifically defined interstate commerce to include any article "with the expectation that they will end their transit, after purchase, in another [state]." Neither the FDCA nor the PHSA have such statutory language.

Simpson was decided in 1920 and involved a statute enacted during the Prohibition era that prohibited taking liquor into a State if the State itself prohibited the manufacture of liquor within its borders. Moreover, the statute in *Simpson* was subsequently repealed and thus *Simpson* is no longer good law.

The *Barnes*, *Vidal* and *Sanders* cases did not even involve the situation where the goods were sold directly to the consumer via an intrastate sale. Instead, *Barnes*, *Vidal* and *Sanders* all involved the interstate shipment of goods from the manufacturer's state to either a broker or distributor located in another state who in turn sold the goods to the consumer.

The only case cited by FDA that is remotely on point is *Drown*. However, *Drown* involved a licensed physician who claimed to have manufactured a "device" (not a food) that could cure cancer and other physical ailments. Moreover, the physician in *Drown* made claims that were simply not true, unlike the situation in this case where all of the Plaintiffs know that they are receiving milk and that their milk is what it purports to be.

In *Drown*, the physician claimed that her device was:

> "efficacious in treating kidney and bladder complications, tipped uterus, extra kidney, painful urination, streptococcus in the urethra and the pyloric

> end of the stomach and bladder, cirrhosis and carcinoma of the right kidney, low function of the left suprarenal gland, pancreas, fibrous adhesions in the brain and meningeal tissue, brain sinus, cystic fluid in the brain and medulla, heart trouble, head pains and noises, explosions in right ear while falling asleep, constipation, pains in the lower back, abcesses, loss of speech and memory, worry, fear and nervousness, conditions of the colon and liver."

Drown v. U.S., 198 F.2d 999, 1002 (9th Cir. 1952). The government, however, presented several expert witnesses (physicians, an engineer and a physicist) who all "expressed the unanimous belief that appellant's instruments are useless for diagnosis or treatment of any human ailment." *Id*. at 1002-1003. Thus, the facts of *Drown* are different from the facts of this case as the purchaser of the product in *Drown* needed protection from the nefariousness of the physician.

Because the *Drown* court had in mind "the broad purpose of the Act, protection of the public health, we believe that Congress intended to prohibit the delivery of a misbranded device by a seller to the purchaser where the seller has knowledge that the purchaser intends to introduce the device into interstate commerce by taking it into another state." *Id*. at 1004. Thus, the reasoning behind the *Drown* case is not applicable here because the Plaintiffs know what it is they are purchasing and they are not being misled by the farmers from whom they purchase their milk. Also, the reasoning of the *Drown* court is inconsistent with the Eighth Circuit's reasoning in *U.S. v. Ruffin*, 490 F.2d 557, 560 (8th Cir. 1974).

Thus, Plaintiffs are not engaged in interstate commerce and FDA is not entitled to summary judgment. Therefore, its motion is not well taken and it should be denied.

Assuming for the sake of argument that Plaintiffs' conduct constitutes interstate commerce, 1240.61 goes beyond the reach of the FDA's authority under the FDCA.

Although Congress gave the FDA the power to regulate "interstate commerce" under the FDCA,[5] the FDA can do so only if there is some form of "activity." *See, e.g., U.S. v. Lopez*, 514 U.S. 549, 558, 115 S.Ct. 1624 (1995) ("Consistent with this structure, we have identified three broad categories of activity that Congress may regulate under its commerce power."). In this case, 1240.61 does not regulate an "activity;" instead, it is a prohibition operating as a mandate that only pasteurized dairy products can be placed and purchased in the stream of interstate commerce.

Congress, let alone the FDA, does not have the authority to mandate that the consuming public must purchase pasteurized dairy products to the exclusion of raw dairy products. *See, e.g., Virginia ex rel. Cuccinelli v. Sebelius*, 728 F.Supp.2d 768, 782 (E.D. Va. 2010) ("Neither the Supreme Court nor any federal circuit court of appeals has extended Commerce Clause powers to compel an individual to involuntarily enter the stream of commerce by purchasing a commodity in the private market."). Thus, FDA cannot mandate that if dairy products are going to be purchased, those products must be pasteurized rather than fresh and unprocessed.

The case of *Florida ex rel. Bondi v. U.S. Dept. of Health and Human Services*, --- F.Supp.2d ----, 2011 WL 285683 (N.D. Fla. 2011) (attached hereto as Exhibit A) is instructive. In that case, the issue was whether the recent health care legislation that mandated the purchase of health insurance was within the ambit of Congress' power to regulate interstate commerce. In *Bondi*, the court held that Congress' power to regulate

[5] Curiously, 1240.61 was promulgated by FDA *not* under the FDCA but instead *under the PHSA* which regulates, in part, "communicable diseases" and not "interstate commerce." In fact, the PHSA, originally enacted in 1944, does not even use the words "interstate commerce" except for the regulation of "biological products" under 42 U.S.C. 262. Query how 1240.61 can prohibit the transportation of raw milk in "interstate commerce" when it is the FDCA that regulates interstate commerce.

interstate commerce does not include the authority to require "everyone to buy a product from a private company (essentially for life) just for being alive and residing in the United States." *Id*. at *20.

In arguing that Congress *did* have the authority to require everyone to purchase health insurance, the Secretary of the Department of Health and Human Services (one of the same defendants in this case and the parent agency of FDA) argued that because health care was a "unique" industry or market, nobody could "opt out" of that market. The court rejected that argument, stating "there are lots of markets—especially if defined broadly enough—that people cannot opt out of. For example, everyone must participate in the food market." *Id*. at *24. The court went on to state that if everybody must participate in the food market, then HHS' argument would mean that "Congress could require that people buy and consume broccoli at regular intervals, not only because the required purchases will positively impact interstate commerce, but also because people who eat healthier tend to be healthier, and are thus more productive and put less of a strain on the health care system." *Id*. The *Bondi* court was not willing to interpret the Commerce Clause as granting Congress the authority to tell us all what to eat.

The *Bondi* court went on to make similar analogies to the transportation and housing industries:

> Similarly, because virtually no one can be divorced from the transportation market, Congress could require that everyone above a certain income threshold buy a General Motors automobile—now partially government-owned—because those who do not buy GM cars (or those who buy foreign cars) are adversely impacting commerce and a taxpayer-subsidized business.
>
> ***

> [Moreover,] virtually no one can opt out of the housing market (broadly defined) and a majority of people will at some point buy a home. The vast majority of those homes will be financed with a mortgage, a large number of which (particularly in difficult economic times, as we have seen most recently) will go into default, thereby cost-shifting billions of dollars to third parties and the federal government. Should Congress thus have power under the Commerce Clause to preemptively regulate and require individuals above a certain income level to purchase a home financed with a mortgage (and secured with mortgage guaranty insurance) in order to add stability to the housing and financial markets (and to guard against the possibility of future cost-shifting because of a defaulted mortgage), on the theory that most everyone is currently, or inevitably one day will be, active in the housing market?

Id. The court concluded no, Congress did not have such powers under the commerce clause and that if "Congress asserts power that exceeds its enumerated powers, then it is unconstitutional, regardless of the purported uniqueness of the context in which it is being asserted." *Id*. at *25.

Such is the case with 1240.61 and 131.110. These rules do not regulate the purchase and distribution of raw milk in interstate commerce; *they outlaw and prohibit it*. Whether or not FDA believes that "drinking raw milk is like playing Russian roulette," FDA cannot prohibit citizens from consuming the foods of their choice when it is legal in all 50 states to consume raw milk. Thus, 1240.61 and 131.110 operate as nothing more than a government mandate that consumers consume only pasteurized dairy products. Because Congress cannot tell the citizens what dairy products they must consume, neither can the FDA. Thus, FDA exceeded its authority under the FDCA and these rules are invalid when applied to Plaintiffs' conduct.

Consequently, FDA is not entitled to summary judgment and its motion should be denied.

B. Plaintiffs' raw milk is not a communicable disease *per se*.

1240.61 was promulgated pursuant to the Public Health Service Act ("PHSA") 42 U.S.C. 201 *et seq*. *See* 57 Fed. Reg. 57343-01, 57344 ("Therefore, under the [PHSA], and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1240 is amended as follows:…."). *See* Appendix, pg. 51. Section 264(a) of the PHSA provides, in part, that the Secretary of Health and Human Services 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." Section 264(b) of the PHSA prohibits the Secretary from issuing regulations allowing for the apprehension or detention of individuals "except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases." In order to apprehend or detain such diseased individuals, however, there must first issue an "Executive order[] of the President upon the recommendation of the Secretary, in consultation with the Surgeon General."

Persons who are "reasonably believed to be infected with a communicable disease in a qualifying stage" and who are either "moving or about to move from a State to another State" or who are "a probable source of infection to individuals" may be apprehended and examined by administrative regulation. *See* Section 264(d)(1). If such a person is infected, "he may be detained for such time and in such manner as may be reasonably necessary." *Id*. However, nothing in Section 264 "may be construed as superseding any provision under State law" except to the extent that "such a provision conflicts with an exercise of Federal authority under this section …." *Id*. at (e).

Section 264 of the PHSA was originally enacted in 1944 and was most recently

amended in 2002. The 2002 Amendment, cited as the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" at Section 142 entitled "Streamlining and clarifying communicable disease quarantine provisions" merely provided for the following changes:

1. the President could act on the recommendation of the Secretary and the Surgeon General rather than acting on the "National Advisory Health Council" as formerly allowed;
2. clarifying the stages of a communicable disease that could serve as cause for apprehension and detention;
3. adding the proviso that nothing was meant to supersede any provision of State law as long as it did not conflict with any Federal authority.

In all other respects, the authority of the Secretary to regulate "communicable diseases" essentially remained the same.

"Communicable disease" is not defined by the PHSA.[6] However, 21 C.F.R. 1240.3 defines "communicable diseases" as, in part, "Illnesses due to infectious agents or their toxic products." Webster's on-line dictionary (www.webster-dictionary.org) defines "infectious agents" as "an agent capable of producing infection." According to Webster, an "infection" is that "which infects, or causes the communicated disease: any effluvium, miasm, or pestilential matter by which an infectious disease if caused." "Toxic" is defined by Webster as "of or pertaining to poison; poisonous; as, toxic medicines." Essentially, a communicable disease is something like tuberculosis, typhoid, malaria,

[6] As mentioned, the PHSA does not even authorize FDA to regulate "interstate commerce." Instead, FDA's authority under the PHSA is to regulate, in part, "communicable diseases."

HIV/AIDS, measles, mumps, rubella, etc.

In this case, FDA is making raw milk that travels across state lines intended for human consumption a communicable disease per se without any evidence of the milk containing an "infectious agent or toxic product." However, a communicable disease is an *illness*, not an agricultural product that is sold or consumed. If FDA's argument is accepted, then raw meat, raw chicken, raw eggs or raw produce could be considered a communicable disease. Thus, there is no legal basis to designate all of Plaintiffs' raw milk as a communicable disease.

Not only is there no legal basis for FDA to conclude that Plaintiffs' conduct constitutes a "communicable disease," there is no factual basis to FDA's conclusion that Plaintiffs' conduct constitutes a communicable disease. According to the affidavit testimony of all the Plaintiffs in this case, there is not and never has been any evidence of sickness from consuming any such raw milk, any evidence that any of the raw milk has been produced under unsanitary conditions, or that any of the raw milk has been contaminated or has contained pathogens. *See* Appendix, pgs. 1-38. Therefore, there is no evidence to support FDA's conclusion that the raw milk being sold by Michael Buck or the raw milk being purchased by all of the other Plaintiffs constitutes a communicable disease.

Consequently, FDA exceeded its authority when it enacted 1240.61 and rendered Plaintiffs' raw milk *per se* a communicable disease. Therefore, FDA is not entitled to a summary judgment.

C. 131.110 has no relationship to honesty and fair dealing.

21 C.F.R. 131.110 was promulgated under Section 341 of the FDCA. Section 341

provides, in part, that FDA may promulgate "standards of identity" and "definitions" for foods in order to "promote honesty and fair dealing in the interest of consumers." "Honesty and fair dealing" is not defined anywhere in the FDCA or in FDA's regulations.

There is little case law that discusses the "honesty and fair dealing" requirement of Section 341. The United States Supreme Court in the case of *Federal Security Adm'r v. Quaker Oats Co*., 318 U.S. 218, 63 S.Ct. 589 (1943) gave deference to the FDA in establishing a standard in order to promote honesty and fair dealing, but said little about what "honesty and fair dealing" meant or how it was to be defined.

Further, the *Quaker Oats* decision merely held it was appropriate for the FDA to define via a "standard of identity" what was "farina" and what was "enriched farina."[7] The United States Supreme Court said such standards were necessary because "the labeling and marketing of vitamin-enriched foods, not conforming to any standards of identity, tend to confuse and mislead consumers." *Id*. at 228. The standards of identities for "farina" and "enriched farina" thus served Congress' purpose to give consumers "who purchase [the product] under that name assurance that they will get what they may reasonably expect to receive." *Id*. at 232.

If "honesty and fair dealing" means that consumers should not be misled or confused when they purchase a food product, it stands to reason that consumers should

[7] FDA defined 'farina' as "a food prepared by grinding and bolting cleaned wheat, other than certain specified kinds, to a prescribed fineness with the bran coat and germ of the wheat berry removed to a prescribed extent. The regulation made no provision for the addition of any ingredients to 'farina'. Regulation 15.140 defined 'enriched farina' as conforming to the regulation defining 'farina', but with added prescribed minimum quantities of vitamin B1, riboflavin,[FN3] nicotinic acid (or nicotinic acid amide) and iron." *Quaker Oats*, 318 U.S. at 222-223.

also be getting what they think they are purchasing, and that they should not be misled into thinking they are purchasing something they do not want. This notion was reinforced by the Eighth Circuit in *Twin City Milk Producers Ass'n v. McNutt*, 122 F.2d 564, 568 (8th Cir. 1941), where the Eighth Circuit stated "there could ordinarily be no arbitrariness involved in using the common or usual name of such a product for regulation purposes." *See also U.S. v. 30 Cases, More or Less, Leader Brand Strawberry Fruit Spread*, 93 F.Supp. 764, 768 (D.C. Iowa 1950) ("the primary purpose and aim of Congress in enacting this important piece of legislation was not the protection of the merchants and traders, but rather the protection of the consuming public."). Thus, "honesty and fair dealing" means the consumer should be purchasing what he/she thinks they are purchasing.

However, just as it is acceptable for FDA to issue a standard of identity for a product that requires the use of the product's "common or usual name," it is *not* acceptable for FDA to "adopt a designation for the purpose of destroying trade in a legitimate food product…." *Twin City Milk Producers Ass'n v. McNutt*, 122 F.2d 564, 568 (8th Cir. 1941). In other words, FDA cannot adopt a "standard of identity" that distorts the meaning of "honesty and fair dealing" and if FDA does so distort, it is the duty of this Court to put a stop to it. "It is for us to ascertain-neither to add nor to subtract, neither to delete nor to distort." *62 Cases, More or Less, Each Containing Six Jars of Jam v. U.S.*, 340 U.S. 593, 596, 71 S.Ct. 515 (1951). Consequently, when it comes to the standard of identity for "milk" this Court must "take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *Id*. at 600.

However, FDA's rule at 131.110 has nothing to do with the "common name" of

milk, or with what "milk" purports to be. Instead, 131.110 is nothing more than a ban on the interstate distribution and sale of a legitimate product that is legal to consume in all 50 states and legal to sell and distribute in 28 states. Indeed, banning raw milk from interstate commerce, a product that all of the Plaintiffs find healthy, wholesome, nutritious and in many instances an improvement to their health[8], is patently illegal. *See U.S. v. Carolene Products Co.*, 304 U.S. 144, 155, 58 S.Ct. 778 (1938) ("If construed to exclude from interstate commerce wholesome food products that demonstrably are neither injurious to health nor calculated to deceive, they are repugnant to the Fifth Amendment.") (concurring opinion).

Thus, 131.110 is not a "standard of identity" that promotes "honesty and fair dealing" for the benefit of consumers; it is FDA's backhanded way of forcing the consumption of pasteurized dairy products and eschewing the consumption of raw dairy products. As previously stated, neither Congress nor the FDA has the authority to compel a consumer to purchase a specific product. *See* discussion *supra*, pgs. 21-23. Consequently, 131.110 goes beyond the scope of FDA's authority under the FDCA and is illegal.

Therefore, FDA is not entitled to a summary judgment and its motion should be denied.

D. FDA's promulgation of 1240.61 is irrational and an illegal attempt to make law.

With respect to Count Four, Plaintiffs argue that 1240.61 and 131.110 exceed FDA's rulemaking authority and in essence prohibit what Congress has *not* prohibited. This constitutes an illegal attempt to make law. FDA's argument on pages 52 and 53 of

[8] *See* Affidavit testimony of the consumer Plaintiffs.

its renewed motion that Plaintiffs have failed to show "that Congress' enactment of the PHSA imposed '[in]sufficient standards upon FDA…'" misses the point.

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." Consequently, only Congress, not the executive, can pass laws that restrict personal liberty. *See 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).

Moreover, 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). Because FDA is "a creature of statute," this Court should be reluctant to allow FDA to "proscribe conduct that Congress did not intend to prohibit." *Guardians Ass'n v. Civil Service Com'n of City of New York*, 463 U.S. 582, 614-615 (1983). *See also Dixon v. United States,* 381 U.S. 68, 74 (1965).

The Eighth Circuit has recognized that HHS has a history of exceeding its statutory authority and of issuing a regulation in excess of that statutory authority. In the case of *St. Joseph's Hosp. of Kansas City v. Heckler*, 786 F.2d 848 (8th Cir. 1986), Congress had enacted the "Medicare Act" which provided that a provider of medical services could seek reimbursement for medical services it had provided. *Id*. at 849-850. The provider was entitled to an administrative hearing in the event its reimbursement

request was either denied or reduced in part. A final appeal was allowed to the "Provider Review Reimbursement Board" ("PRRB"). *Id*. The issue in *St. Joseph's* was whether the provider had filed a timely appeal.

The Medicare Act required all appeals to the PRRB to be filed within 180 days of the final adverse action, yet the Secretary of HHS (the same Defendant in this case) had issued a promulgation that authorized the PRRB to extend that 180 day deadline "for good cause shown." *Id*. at 850. In *St. Joseph's*, the provider admitted it did not file its appeal within 180 days. The Eight Circuit in *St. Joseph's* struck down the regulation, stating "we necessarily conclude that the Secretary had no authority to promulgate a regulation that effectively expanded the jurisdiction of the PRRB to entertain untimely appeals." *Id*. at 852. The Eighth Circuit concluded the regulation was a mere nullity because "the regulation adopted by the Secretary is inconsistent with the authority granted to the Board by Congress in the Medicare Act…." *Id*. at 853.

So it is in this case. For Count Four, 1240.61 and 131.110 exceed FDA's authority because neither the FDCA nor the PHSA give FDA the authority (1) to *completely ban* citizens from traveling across state lines with legally purchased raw dairy products in their possession, or to mandate the consumption of pasteurized dairy products at the expense of raw dairy products; (2) to designate such legally purchased raw dairy products that are taken across State lines by Plaintiffs as an "illness" or "communicable disease" *per se*, or (3) to deem misbranded a product that is what it purports to be. In addition, 1240.61 was promulgated under the authority of the PHSA and it bans the interstate transport of raw milk in final package form intended for human consumption, yet nothing in the PHSA authorizes FDA to regulate "interstate commerce" of dairy

products. Thus, 1240.61 and 131.110 prohibit what Congress did *not* intend to prohibit and they are not in accordance with FDA's regulatory authority.

With respect to Count Five, Plaintiffs allege that Plaintiff Wagoner, as the agent for Plaintiff Cooper, would retrieve Cooper's raw milk from the South Carolina farmer and bring it back with him to South Carolina for delivery to Cooper.[9] Under this theory, Plaintiffs assert that if an individual has the right to cross state lines with raw dairy products in their possession (e.g., Cooper) it would not be rational to forbid that individual's agent (e.g., Wagoner) from crossing state lines with raw dairy products in the agent's possession. Because 1240.61 and 131.110 are not rationally related to any governmental interest in preventing an agent for accomplishing what an individual can accomplish, they violate substantive due process and must be struck down as applied to Wagoner and Cooper. *See, e.g., U.S. v. Buckner*, 894 F.2d 975, 978 (8th Cir. 1990) (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."); *Salcido ex rel. Gilliland v. Woodbury County, Iowa*, 66 F.Supp. 2d 1035, 1049 (N.D. Iowa 1999) (J. Bennett) ("Although 'rational basis' review is deferential, it is not entirely toothless: Even rational basis review places limitations on states by prohibiting arbitrary or irrational classifications or laws motivated by the desire to harm an unpopular group.").

For example, 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 legally

[9] Wagoner and Cooper acknowledge that since FDA's raid and seizure of Wagoner's truck in October 2009 they have each separately traveled to South Carolina to retrieve their own raw milk, and that Wagoner has not acted as Cooper's agent since October 2009. However, as explained in Plaintiffs' Resistance (Doc. #15-1) to FDA's initial motion to dismiss, this Hobson's choice (act as an agent or not act as an agent?) creates standing and presents a claim for relief for which this Court can provide redressability.

obtained in South Carolina by Cooper's agent, Wagoner. Likewise, raw milk in final package form that is legally obtained in South Carolina by Wagoner, Cooper's agent, is no less safe than if that same milk was legally picked up by Cooper herself. Consequently, if Cooper can purchase raw milk in South Carolina and can take it back to her home state of Georgia to consume it, she should be allowed under substantive due process to have Wagoner pick it up for her and bring it back to her in Georgia.

The same analysis can be applied to Plaintiff Michael Buck, the farmer in this case. 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. In other words, there is no rational relation between allowing Buck to legally sell raw milk in South Carolina to a South Carolina resident who consumes the milk in South Carolina, yet prohibiting Buck from legally selling that same milk to a person who consumes it in another State. The milk is the same in both instances and the consumer makes an informed choice about what he/she is purchasing.

Thus, because 1240.61 and 131.110 are not rationally related to any legitimate public interest, they should be struck down as applied to Plaintiffs' conduct.

Therefore, FDA is not entitled to a summary judgment and its motion should be denied.

E. FDA's reliance on *Public Citizen v. Heckler* is misplaced.

FDA argues that it was "ordered" to promulgate 1240.61 by the court in *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D.D.C. 1986) ("*Heckler II*"). However,

FDA's reliance on *Heckler II* is misplaced.

To begin, FDA did not follow the *Public Citizen* court's mandate. Specifically, the court in *Heckler II* ordered FDA to promulgate a regulation under the FDCA that addressed the "sale" of raw dairy in "interstate commerce." FDA, however, did not regulate the "sale" of raw milk, it promulgated a regulation that *banned raw dairy completely* from interstate commerce. In addition, FDA banned the interstate *transport* of raw dairy across states lines even when the conduct involved did not involve "interstate commerce" as defined by 21 U.S.C. 321(b), for example, when a resident of one state travels to another state to make the purchase. Thus, FDA's actions contravened the mandate of the *Heckler II* court.

Moreover, and with all due respect to that court, *Heckler II* is flat out wrong. Plaintiffs have not discovered a case whereby an Article III court can Order an Article II executive agency to perform a ministerial or discretionary function. In addition, Plaintiffs have not discovered a case whereby an Article III court can Order an Article II executive agency to ban the interstate sale, transport or distribution of a food product that is legal to consume in all 50 states.

In fact, there are actually two *Public Citizen* cases, the one cited by FDA in its motion and a predecessor at 602 F. Supp. 611 (D.D.C. 1985) ("*Heckler I*"). Taken together, and with all due respect to that court, the two *Heckler* cases represent an extreme case of judicial activism. In *Heckler I*, the FDA received a citizen petition from a group that petitioned FDA to ban the sale of raw dairy products in interstate commerce. FDA failed to act on the petition in a timely manner and the court in *Heckler I* Ordered FDA to take action on the citizen petition.

In compliance with *Heckler I's* mandate, the FDA took action on the petition, refused to impose a ban on the sale of raw dairy in interstate commerce, *and denied the petition*. *See Public Citizen v. Heckler*, 653 F. Supp. 1229, 1231 (D.D.C. 1987) ("*Heckler II*"). In denying the petition and refusing to ban the interstate sale of raw milk, FDA's stated reason was that "a federal ban would not be the most effective or appropriate means of dealing with the health problems posed by unpasteurized milk and milk products…." *Id*. at 1235. Going further, FDA stated that "the problems created by unpasteurized milk and milk products are most appropriately dealt with at the state and local level" and that banning raw milk from interstate commerce would "have a minimal effect on" public health. *Id*. Finally, FDA stated it did not have the legal authority to ban the intrastate sale of raw milk. *Id*. Thus, FDA denied the petition in response to *Heckler I*.

Notwithstanding FDA's stated reasons for denying the petition and for refusing to impose a ban on either the interstate or intrastate sale of raw dairy products, the *Heckler II* court substituted its judgment for that of FDA and ordered FDA to ban the interstate sales of raw dairy product anyway.[10] Not only did the *Heckler II* court substitute its judgment for that of the FDA, it ordered FDA to institute an interstate ban on the sale of raw dairy products under the PHSA when there is no authority under the PHSA for FDA to regulate "interstate commerce." Thus, this reinforces the notion that *Heckler II* is wrong and is an extreme case of judicial activism.

[10] The irony of *Heckler I* and *Heckler II* is that FDA, for several years, *refused to ban* the sale of raw dairy in interstate commerce and only did so after being ordered to do so by *Heckler II*, while currently it has had pending before it for over two years a citizen petition requesting that FDA rescind the ban on the sale of raw dairy in interstate commerce yet FDA *refuses to rescind the ban*. *See* Affidavit of Mark McAfee, Doc. #15-5.

Consequently, FDA is not entitled to summary judgment and its motion should be denied.

IV. 1240.61 and 131.110 violate Plaintiffs' right to travel across State lines with raw milk in their possession.

The United States Supreme Court has long recognized a constitutional right to travel. *See, e.g., United States v. Guest*, 383 U.S. 745, 757, 86 S.Ct. 1170, 1178, 16 L.Ed.2d 239 (1966); *Shapiro v. Thompson*, 394 U.S. 618, 629 (1969) *overruled in part on other grounds; Attorney General of New York v. Soto-Lopez*, 476 U.S. 898, 901-902 (1986); *Saenz v. Roe*, 526 U.S. 489, 501 (1999). The constitutional right to travel "is a virtually unconditional personal right, guaranteed by the Constitution to us all." *Shapiro v. Thompson*, 394 U.S. 618, 643 (1969) (Stewart, concurring). Therefore, "[a]ny classification which serves to penalize the exercise of that right, unless shown to be necessary to promote a compelling governmental interest, is unconstitutional." *Id*. at 634. *See also Dr. John's, Inc. v. City of Sioux City, Iowa*, 389 F.Supp. 2d 1096, 1121 (N.D. Iowa 2005) (J. Bennett) ("'Strict scrutiny' requires that, to be constitutional, a regulation must be '*narrowly tailored* to serve a *compelling* state interest.'") (Emphasis in original).

A law "may not impose a penalty upon those who exercise a right guaranteed by the Constitution." *Harman v. Forssenius*, 380 U.S. 528, 540, 85 S.Ct. 1177, 1185, 14 L.Ed.2d 50 (1965). Indeed, our "Constitutional rights would be of little value if they could be . . . indirectly denied." *Id*. Laws that have "no other purpose or effect than to chill the assertion of constitutional rights by penalizing those who choose to exercise them" are "patently unconstitutional." *U.S. v. Jackson*, 390 U.S. 570, 581 (1968). Regardless of whether that classification is a state or federal law, it must be struck down if it does not promote a compelling governmental interest. *See, e.g., Shapiro v.*

Thompson, 394 U.S. at 642.

With respect to the right to travel, this means that a state or federal law that does not promote a compelling governmental interest will be struck down if it "implicates the right to travel when it actually deters such travel, (citations omitted), when impeding travel is its primary objective, (citations omitted), or when it uses 'any classification which serves to penalize the exercise of that right.'" *Attorney General of New York v. Soto-Lopez*, 476 U.S. 898, 903 (1986).[11]

Therefore, because a constitutional right to travel exists, the question in this case becomes the scope and extent of the right to travel, i.e., can one travel across State lines with legally purchased raw milk or raw dairy products in one's possession. Thus, the right to travel cannot be trammeled upon by a punitive measure, for example, 1240.61 and 131.110.

In this case, Plaintiffs' complaint alleges and FDA does not deny that it is legal to consume raw milk and raw dairy products in all 50 States of this country. FDA does not presume to argue that the federal government can regulate the *consumption* of raw milk and/or raw dairy. Rather, FDA argues that it can regulate the "interstate commerce" of raw dairy and/or raw dairy products.

However, as Plaintiffs alleged in their complaint and as FDA has already admitted in this case, it is legal to purchase raw milk and/or raw dairy in at least 28 states.

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[11] *See also Crandall v. State of Nevada*, 73 U.S. 35, 47, (1867) (law that required Nevada railroads and stagecoach operators to collect a tax from each individual passenger who entered or left Nevada violated right to travel); *Dunn v. Blumstein* 405 U.S. 330, 339-342 (1972) (law that imposed a durational requirement in order to exercise the right to vote in Tennessee violated right to travel, even when none of the litigants had been deterred from voting); *Zobel v. Williams*, 457 U.S. 55, 62, fn. 9 (1982) (law that distributed income derived from state oil resources in Alaska to residents based on length of residency violated equal protection and right to travel).

Because it is legal to purchase these products in at least 28 states, there is nothing to prohibit citizens from traveling into one State to legally purchase these products in those 28 states when the law of the citizen's state of residence prohibits such purchase. For example, an Iowa resident (where it is illegal to purchase raw dairy) can travel into Nebraska to legally purchase raw dairy, and there is no law in Iowa that prohibits an Iowa resident from doing this.

Thus, 1240.61 and 131.110 operate as nothing more than a barrier on the free movement across State lines with raw milk and raw dairy products in one's possession, even when those products are legally purchased in one state. Consequently, 1240.61 and 131.110 constitute a "classification which serves to penalize the exercise of" the fundamental right to travel. *See Shapiro v. Thompson*, 394 U.S. 618, 634 (1969).

Since these regulations impact a right protected by the Constitution, strict scrutiny applies yet there is no compelling interest served by these regulations. For instance, if the alleged interest behind 1240.61 and 131.110 is to prevent citizens from having access to raw milk, that interest is not served because there are 28 states that allow the sale of raw milk and/or raw dairy products. Thus, 1240.61 and 131.110 do not limit access to raw milk products.

If the alleged interest behind 1240.61 and 131.110 is to curtail the interstate distribution of raw dairy products, that interest also is not served because 28 states allow the sale of raw dairy products and there is no state law anywhere that prohibits one of its residents from traveling to a neighboring state to purchase or to consume raw dairy products in a state where it is legal to do so. Indeed, the Privileges and Immunities clause of the Constitution allows the residents of one state to enjoy the privileges and

immunities of the residents of another state. Again, residents in a state where it is illegal to purchase raw dairy products may simply travel to another state where it is legal to purchase raw dairy products. Thus, 1240.61 and 131.110 do not limit interstate access to raw milk.

If the alleged interest behind 1240.61 and 131.110 is to prevent individuals from coming in contact with "communicable diseases," this interest is not served because there are 28 states that allow the sale of raw dairy products. Moreover, the blanket prohibition of 1240.61 and 131.110 is overly broad because it is irrational to presume that *all* raw dairy products, *per se*, contain "infectious agents" or "toxic products" such that they meet the definition of "communicable disease." Thus, 1240.61 and 131.110 do not limit contact with "communicable diseases."

If the alleged interest behind 1240.61 and 131.110 is to warn individuals about consuming a product that might make them sick, this interest is not served because 28 states allow the sale of raw dairy products. Moreover, 1240.61 and 131.110 are not narrowly tailored because a warning label would provide just as much protection.[12]

If the alleged interest behind 1240.61 and 131.110 is to prevent the introduction into interstate commerce of "potentially dangerous products," this interest is not served by the multitude of products regulated by FDA that can be freely transported across state lines, e.g., cigarettes, drugs and medicines. Indeed, in the year 2005 alone, 4,649 people died from obesity, 1,096 people died from unspecified mental and behavioral disorders due to use of tobacco. In addition, multiple drugs approved by FDA cause multiple harmful side effects. *See* Appendix, pg. 237-251. Moreover, three people died in 2007

[12] 21 C.F.R. 101.17 pertains to unpasteurized juices and provides, in part, that a warning label on a juice container is an acceptable alternative to pasteurizing the juice.

from consuming *pasteurized* milk. *See* Appendix, pg. 232-235. Thus, there is no compelling reason why raw dairy products should be prohibited from being taken across state lines yet these other dangerous products are allowed.

Quite simply, there is no purpose behind 1240.61 and 131.110 except to "chill" or "obstruct" or "interfere with" or "restrict" the right to travel across state lines with raw dairy in one's possession. Indeed, and as explained before, 1240.61 and 131.110 would not prevent a tanker truck containing 3,5000 gallons of raw milk from crossing state lines when some or all of its raw milk was subsequently distributed for consumption yet it prohibits Plaintiffs from taking their miniscule amounts of raw milk across state lines. Therefore, 1240.61 and 131.110 constitute an impermissible restriction on the constitutionally protected right to travel and do not survive strict scrutiny.

Our country was founded on the notion that we all have inherent, inalienable rights that the government cannot take away from us except by due process. "Government of the people, by the people, for the people" as Abraham Lincoln said. If a person does not have the right to take raw dairy across state lines, what will be the next product that the government will prohibit its citizens from taking across state lines? Pets, pornography, alcohol, cigarettes, medicines, prescription drugs, live chickens, live cows, raw eggs, raw produce, raw herbs, uncooked meat, fruit? When will it end?

As the United States Supreme Court has stated, the history of our nation reflects the "traditional and common-sense notion that the Due Process Clause, like its forebear in the Magna Carta, (citation omitted) was intended to secure the individual from the arbitrary exercise of the powers of government." *Collins v. City of Harker Heights, Tex.*, 503 U.S. 115, 127, fn. 10, 112 S.Ct. 1061 (1992) (citation omitted). Indeed, due process

"forbids the government to infringe certain 'fundamental' liberty interests *at all,* no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Reno v. Flores*, 507 U.S. 292, 302 (1993) (emphasis in original).

As the United States Supreme Court stated in *Lawrence v. Texas*, 539 U.S. 558 (2003), the concept of liberty "presumes an autonomy of self that includes freedom of thought, belief, expression, and certain intimate conduct." *Id*. at 562. Therefore, it behooves this Court to consider the admonition of Justice Kennedy in his concurring opinion in *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 112 S.Ct. 2130 (1992):

> As Government programs and policies become more complex and farreaching, we must be sensitive to the articulation of new rights of action that do not have clear analogs in our common-law tradition. Modern litigation has progressed far from the paradigm of Marbury suing Madison to get his commission, *Marbury v. Madison,* 5 U.S. (1 Cranch) 137, 2 L.Ed. 60 (1803), or Ogden seeking an injunction to halt Gibbons' steamboat operations, *Gibbons v. Ogden,* 22 U.S. (9 Wheat.) 1, 6 L.Ed. 23 (1824).

Id. at 580.

In this day and age many people, including Plaintiffs, are now eschewing and opting out of the industrial-sized, centralized, subsidized, government-sanctioned food production system. Instead, they are turning toward local farmers who are producing nutrient-dense foods that will restore their health. Although this national "food rights" movement was probably not contemplated by the Founding Fathers, it should now be recognized by this Court as a component of Plaintiffs' liberty interest in having access to the foods of their choice.

Accordingly, the right to travel should include the right to have raw dairy products in one's possession when traveling from State to State. Therefore, FDA is not

entitled to summary judgment and its motion should be denied.

V. 1240.61 and 131.110 violate Plaintiffs' right of privacy to consume the food of their choice.

When analyzing a substantive due process claim, the reviewing court should begin "by examining our Nation's history, legal traditions, and practices." *Washington v. Glucksberg*, 521 U.S. 702, 710 (1997). *See also Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705 (1973); *Moore v. East Cleveland,* 431 U.S. 494, 503, 97 S.Ct. 1932, 1937-1938, 52 L.Ed.2d 531 (1977) (plurality opinion); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 851 (1992). These factors include "our philosophical, legal, and cultural heritages." *Washington v. Glucksburg*, 521 U.S. at 711. As described below, the right to consume the food of one's choice for oneself and one's family is consistent with this country's heritage since 1607. Moreover, the requirement that milk be "pasteurized" is a recent event in this nation's history. Finally, there never was any prohibition against taking raw dairy across state lines until 1973, and no full and complete prohibition until 1987.

This country's citizens have been drinking raw milk and consuming raw dairy products like cheese, kefir, yogurt and butter, from the 1600s to the present. In fact, USDA keeps statistics on the number of gallons of raw milk consumed by dairy farmers all over the country. As an example, from 1996 – 2005, USDA estimates that farmers consumed nearly 2 billion pounds of raw milk as either fluid milk or cream at the farm where the raw milk was produced. *See* National Agriculture Statistics Service data at http://www.nass.usda.gov/Publications/Ag_Statistics/2007/2007.pdf, table 8-16. (Agricultural Statistics 2007, Chapter 8, Dairy and Poultry Statistics). *See* Appendix, pg. 68.

Indeed, *it is now and it has always been legal to consume raw dairy products in all 50 states*. It has never been illegal in any state to consume raw dairy products. Therefore, the nation's history demonstrates that there is a right to consume the raw dairy products of one's choice.

The requirement that all milk in "final package form" that crosses state lines must first be "pasteurized" is a recent phenomenon that does not have a basis in this country's 300 year heritage. Indeed, a pasteurization plant in the United States was not required from the time Jamestown was settled in 1607 until the recent present when 131.110 was promulgated, which as FDA has already admitted in this case was 1973. Moreover, the federal model Pasteurized Milk Ordinance ("PMO")[13] did not require pasteurization until 1965 and the first State (Michigan) did not require pasteurization until 1948. Therefore, the requirement that all fluid milk be pasteurized is a very recent phenomenon in only some States and does not have any basis in this country's prior 300 year legal heritage.

Moreover, FDA has already admitted in this case that it only became illegal to take raw dairy products across state lines as recently at 1987, the year that 1240.61 was promulgated. *Indeed, before 1987 it was legal to carry raw dairy products across state lines and it was a right recognized and defended by FDA itself*.[14] Consequently, there is

[13] In 1924, the FDA developed the standard milk ordinance, known today as the Pasteurized Milk Ordinance (PMO). The PMO is a model regulation which States are free to adopt or not, and contains provisions governing the production, processing, packaging and sale of Grade A milk and milk products. Section 9 of the PMO states, in part, "only Grade 'A' pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments." While 47 States have adopted most or all of the PMO, many of those 47 States have excluded Section 9 and still allow the sale of raw milk intrastate.

[14] *See Public Citizen v. Heckler*, 653 F. Supp. 1229, 1235 (D.D.C. 1987) ("*Heckler II*") (In denying a citizen petition to ban the interstate sale of raw milk, FDA stated, *inter alia*,

no social heritage in this country that citizens cannot have access to raw milk or that they could not take it with them across state lines. To the contrary, citizens have been taking raw milk anywhere they please since at least the 1600s.

Food is integrally connected to one's health. The foods people consume literally form the building blocks of their health, and science is continually learning more about the beneficial impacts of enzymes, probiotics, and other components in raw milk, much of which was unknown just a few decades ago.[15] Nutrition is a recognized field of health care and choosing one's nutrition is a fundamental part of choosing one's medical treatment. To paraphrase Hippocrates, "let your medicine be your food and let your food be your medicine."

Food is also central to traditional family life, with the kitchen table at the heart of the home. The right to choose what foods to provide to one's children is just as integral, if not even more so, than the right to choose what schools to send them to. Accordingly, the right to privacy should include the right to feed oneself and one's family raw dairy products because the consumption of raw dairy products has been deeply rooted in this country's history and tradition for over 300 years.

The issue of whether or not we all have the right to consume the food of our choice and to be responsible for our health is a case of first impression in the federal courts. It should go without saying that the Founding Fathers did not think this would even be an issue when they adopted the Constitution or Bill of Rights, yet FDA is making

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that "a federal ban would not be the most effective or appropriate means of dealing with the health problems posed by unpasteurized milk and milk products….").

[15] *See* Appendix, pgs. 105-140, 161-231.

it an issue. Guidance on this issue can be gleaned from other Supreme Court cases that have dealt with the issues of liberty, right to privacy, and substantive due process.

For example, the Supreme Court has vindicated the following rights:

- the right to the education and raising of one's own children. *See Meyer v. Nebraska*, 262 U.S. 390 (1923);
- the right to send one's children to the school of one's choice. *See Pierce v. Society of the Sisters of the Holy Names of Jesus and Mary*, 268 U.S. 510, 45 S.Ct. 571 (1925);
- the right to have children. *See Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942);
- the fundamental right to be free from bodily invasions. *See Rochin v. California*, 342 U.S. 165 (1952);
- the right to marital privacy and to be left alone. *See Griswold v. Connecticut*, 381 U.S. 479 (1965);
- the right to marry, whether within or outside of one's own race. *See Loving v. Virginia*, 388 U.S. 1 (1967);
- the right to possess or view pornography in the privacy of one's own home. *See Stanley v. Georgia*, 394 U.S. 557 (1969);
- the right to receive contraceptives, since all persons have the fundamental right to beget or not beget a child. *See Eisenstadt v. Baird*, 405 U.S. 438 (1972);
- the right of a woman to have an abortion. *See Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705 (1973); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833

(1992);

- the right to refuse medical treatment, even life saving treatment. *See Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990);
- the right of parents to raise their children. *See Troxel v. Granville*, 530 U.S. 57, 65 (2000);
- the right to engage in consensual sexual conduct. *See Lawrence v. Texas*, 539 U.S. 558, 578 (2003).

Based on this long line of precedent and the nation's heritage on the consumption of raw dairy products as discussed *supra*, the right to consume the foods of one's choice should also be a protected, fundamental right. As such, 1240.61 and 131.110 are subject to a strict scrutiny analysis and must be struck down unless they are narrowly tailored to meet a compelling governmental interest. *See Dr. John's, Inc. v. City of Sioux City, Iowa*, 389 F.Supp. 2d 1096, 1121 (N.D. Iowa 2005) (J. Bennett) ("'Strict scrutiny' requires that, to be constitutional, a regulation must be '*narrowly tailored* to serve a *compelling* state interest.'") (Emphasis in original).

What good are all the fundamental rights mentioned above if a person cannot consume the food of his/her own choice? In essence, the public (government) should not have any say in what foods the Plaintiffs choose to consume for themselves and their families. Thus, government does not have the right to tell Plaintiffs what foods they can or cannot eat. To prevent a person from consuming the foods of their own choice is a denial of that person's liberty. Therefore, because Plaintiffs are engaging in a fundamental right and their conduct does not involve the public's health, safety or welfare, 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs.

The Declaration of Independence states as follows: "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness." As the United States Supreme Court recognized in *Stanley v. Georgia*, 394 U.S. 557 (1969), the makers of the Constitution:

> undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone-the most comprehensive of rights and the right most valued by civilized man.

Id. at 564. *See also* the dissent in *Henne v. Wright*, 904 F.2d 1208, 1216-1217 (8th Cir. 1990) ("The Founders of this Nation deeply believed that the individual took primacy over government. People existed, and had rights, before there was such a thing as government. Government might protect or recognize rights, but rights, some of them anyway, existed before government and independently of it, and would continue to exist after government had been destroyed. The source of rights was not the State, but, as the Declaration of Independence put it, the "Creator."). Thus, Plaintiffs have the right to be left alone by their government when it comes to their food choices.

With respect to liberty, the Constitution protects a person from "unwarranted government intrusions into a dwelling or other private places" and extends to "other spheres of our lives and existence, outside the home, where the State should not be a dominant presence." *Lawrence v. Texas*, 539 U.S. 558, 562 (2003). At the central core of liberty is "the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define

the attributes of personhood were they formed under compulsion of [government].”). *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 851 (1992). Thus, Plaintiffs should be able to define themselves by the foods they consume.

Our liberties are protected by substantive due process, whose purpose is “to prevent government from abusing [its] power, or employing it as an instrument of oppression” (citations and quotations omitted) and to “protect the people from the State, not to ensure that the State protect[s] them from each other.” *DeShaney v. Winnebago County Dept. of Social Services*, 489 U.S. 189, 196 (1989). Substantive due process also “forbids the government to infringe certain ‘fundamental’ liberty interests *at all,* no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest.” *Reno v. Flores*, 507 U.S. 292, 302 (1993) (emphasis in original). If the right of privacy means anything, it is “the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters [that] fundamentally affect[] a person….”). *Eisenstadt v. Baird*, 405 U.S. 438, 459 (1972). Thus, Plaintiffs should be free from governmental harassment when it comes to their health and their food choices.

Contrary to FDA’s argument on page 48 of its renewed motion to dismiss that “no known reported case has ever recognized a fundamental right to consume a particular food,” basic rights guaranteed under the Constitution do not require case law to justify their existence. That is because the Constitution is a flexible document. “Had those who drew and ratified the Due Process Clauses of the Fifth Amendment or the Fourteenth Amendment known the components of liberty in its manifold possibilities, they might have been more specific.” *Lawrence v. Texas*, 539 U.S. 558, 578 (2003). However, the

drafters could not see into the future and "did not presume to have this insight" into the specific nature of all of the rights we enjoy at the endowment of our Creator. *Id*. at 578-579.[16] Nonetheless, as the Constitution endures, "persons in every generation can invoke its principles in their own search for greater freedom." *Id*. at 579. Therefore, FDA's suggestion that no fundamental rights exist until a court recognizes that right should be rejected.

Thus, this Court should recognize that the right to privacy includes the right to consume for oneself and one's family the foods of choice, and the right to be healthy. Therefore, FDA is not entitled to summary judgment and its motion should be denied.

VI. FDA's "dangers of raw milk" and "lack of enforcement action" arguments are red herrings.

FDA argues that, based on the administrative record it has filed in this case, raw milk is bad for a person's health and does not have any healthy benefits when consumed. That argument is not relevant to whether FDA's interpretation and application of 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs' conduct. Again, Plaintiffs are not challenging the facial validity of 1240.61 and 131.110 nor are they challenging whether FDA complied with applicable notice and hearing rule making requirements of the federal Administrative Procedure Act ("APA").

Instead, and as explained above in Section III, Plaintiffs are arguing that FDA does not have the substantive authority to issue a rule that requires consumers to purchase

[16] *See also* the 9th Amendment, which provides as follows: "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." For example, each private citizen possesses a right to choose his or her own style and length of hair and such choice is protected by the 9th Amendment. *See, e.g., Stradley v. Andersen*, 349 F.Supp. 1120 (D.C. Neb. 1972). If we have the right to our own hairstyle, we should have the right to our own health.

only pasteurized dairy products, that makes Plaintiffs' agricultural products a "communicable disease" *per se*, or to issue an alleged "standard of identity" that has nothing to do with promoting honesty and fair dealing, especially when the "standard of identity" operates as a mandate that consumers purchase only pasteurized dairy products instead of raw dairy products. *See* cases cited *supra*, Section III. As a result, the administrative record that was filed in support of the issuance of 1240.61 and 131.110 is not relevant to the matter at hand.

However, and assuming for the sake of argument that the health effects of consuming raw milk are relevant, FDA's "administrative record" is unreliable for several reasons:

a. it is 25 years old;
b. it does not include recent scientific research demonstrating the health benefits of consuming raw milk;
c. it does not include older studies demonstrating the health benefits of consuming raw milk;
d. it does not contain any studies on the deaths caused by the consumption of pasteurized milk;
e. it does not contain any statistical data from the Centers for Disease Control on outbreaks associated with the consumption of pasteurized dairy products;
f. it is a record that refers to raw milk that must of necessity be pasteurized before it is consumed, rather than to raw milk that is intended to be consumed in its fresh, unprocessed, raw state, which as explained by Michael Buck constitute two different approaches to the production of raw milk.

The evidence submitted by Plaintiff in its resistance to FDA's motion, however, is replete with current scientific research on the health benefits of consuming raw dairy products and also contains other data demonstrating the unreliability of FDA's record. For example, FDA's record does not contain the articles by Andersson, Braun-Fahrlander, Callaway, Gregory, Hess, Kagkli, Kramer, Mattick, Mendelson, Pitt, Rist, Ryan, Scott, Waser and Woessner. *See* Appendix, pgs. 119-140, 161-231. Plaintiffs' evidence also includes HHS's/CDC's evidence of illness and even death from consuming pasteurized dairy products, as well as evidence of the beneficial probiotic effects of raw milk, beneficial effects that dead, pasteurized milk does not have. *See* Appendix, pgs. 105-118, 141-148, 154-155, 232-235. In addition, Plaintiffs' evidence contains several of the Plaintiffs testimonials regarding their increased health benefits from consuming their raw milk. *See* Appendix, pgs. 1-38.

Significantly, Plaintiffs' evidence explains the difference between the two types of raw milk that is produced in this country. FDA's record is replete with references to only those large scale dairy operations that produce milk under such unsanitary conditions that it *must* be pasteurized before it is consumed. FDA's record does not address the other way that raw milk is processed, a process so completely different from the typical raw milk operation that the milk is intended to be consumed in its fresh, unprocessed, raw state. *See* Appendix, pgs. 9-12. Consequently, and at a minimum, the evidence submitted by Plaintiffs in resistance to FDA's motion for summary judgment creates a genuine issue of material fact that serves to defeat FDA's motion.

FDA also puts a new spin on its argument that it has not enforced the law against Plaintiffs, now arguing that this prevents Plaintiffs from making an "as applied"

challenge. *See* FDA's motion for summary judgment, Section IV.C. However, the mere fact that FDA has not taken any enforcement action against any of the Plaintiffs does not mean that 1240.61 and 131.110 does not apply to Plaintiffs' conduct. *See Bankamerica Corp. v. U.S.*, 462 U.S. 122, 131, 103 S.Ct. 2266 (1983) ("It is true, of course, that '[a]uthority granted by Congress ... cannot evaporate through lack of administrative exercise'; the mere failure of administrative agencies to act is in no sense 'a binding administrative interpretation' that the Government lacks the authority to act.") (citations omitted). To the contrary, FDA has admitted that 1240.61 and 131.110 apply to Plaintiffs' conduct. *See* Appendix, pgs. 40-48. Because FDA has already admitted that 1240.61 and 131.110 apply to Plaintiffs' conduct, Plaintiffs are entitled to challenge the applicability of these regulations to their conduct whether or not FDA exercises its discretion to bring an enforcement action against. Thus, FDA's failure to enforce the law against Plaintiffs is also a red herring.

Consequently, FDA is not entitled to a summary judgment and its motion should be denied.

VII. Conclusion

"It is dangerous to be right when the government is wrong."-Voltaire

For the reasons stated above, and for the reasons stated in Plaintiffs' earlier resistance to FDA's earlier motion to dismiss, FDA is not entitled to summary judgment and its motion should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

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