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 MOTION TO DISMISS

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I. Introduction.

This nation's history is replete with examples of government oppressing its people, depriving its citizens of those basic, fundamental, inalienable rights that are endowed to them by their Creator. Yet government eventually learns of its errors and eventually throws off the yoke of oppression.

For example, prior to 1865, the government said it was okay for a citizen to own a slave. Today, slavery is abhorrent to society.[1]

Prior to 1920, the government told women that they did not have the right to vote. Today, women have the right to vote and are an integral component of this country's strength and foundation.[2]

Prior to 1954, the government told the races that they had to be segregated, and "separate but equal" was the norm in race relations. Today, segregation is a thing of the past and equality is the aspiration of people everywhere.[3]

Prior to 1967, the government told individuals that they could not marry outside of their race. Today, racial diversity is celebrated in towns and cities all over the

[1] The Thirteenth Amendment was ratified in 1865.
[2] The Nineteenth Amendment was ratified in 1920.
[3] *Brown v. Board of Education* was decided in 1954.

country.[4]

Prior to 1993, the government told parents that they did not have the right to home school their children. Today, home schooling is viewed as an acceptable alternative to government sponsored education and is widespread throughout the nation.[5]

Currently, unfortunately, government is telling its citizens that they do not have the right to travel across state lines with raw dairy products in their possession; that individuals do not have the right to a healthy body; and that parents do not have the right to feed themselves and their families the foods of their choice.[6] This notion is paternalistic and treats its citizens as wards of the state who are incapable of making decisions for themselves.

This case is about liberty and freedom and presents an issue of first impression in the federal courts that addresses this current form of oppression. Plaintiffs represent the tipping point of a food rights movement that involves knowing one's source of food; becoming responsible for what foods go into one's body; becoming responsible for ones health; ensuring that one's family and children grow up healthy with an excellent immune system; and engaging in conduct with similar like minded individuals to promote a healthier and happier America. Since "you are what you eat," literally, the choice as to what foods to consume is fundamental to one's bodily integrity and is one of the foundations of family life.

As a case of first impression, this Court will be issuing a decision that will have profound impacts across the country. The decision of this Court will either ensure that

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[4] *Loving v. Virginia* was decided in 1967.
[5] The Religious Freedom Restoration Act was enacted in 1993. *See also* Home School Legal Defense Association website at http://www.hslda.org/about/history/1993.asp.
[6] FDA's motion to dismiss at pages 22-27.

people have fundamental rights endowed to them by their Creator, or that the people have no rights except those that are conferred upon them by government. In essence, this case asks this Court to decide whether the people control the government, or whether the government controls the people.

Specifically, Plaintiffs are alleging that 21 C.F.R. 1240.61 and 131.110 are unconstitutional as applied to their conduct. 21 C.F.R. 1240.61 (hereinafter "1240.61") was promulgated in 1987 pursuant to Section 264 of the Public Health Service Act ("PHSA") for the control of communicable diseases and provides, in part, as follows:

> no person shall cause to be delivered into interstate commerce or shall sell or otherwise distribute [any milk or milk product] in final package form for direct human consumption [unless the milk or milk product has first been] pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized.

For its part, 21 C.F.R. 131.110 (hereinafter "131.110") was promulgated in 1973 pursuant to Section 341 of the Food, Drug and Cosmetic Act ("FDCA") and provides, in part, that the standard of identity for all milk "that is in final package form for beverage use shall have been pasteurized or ultrapasteurized."

Consequently, 1240.61 and 131.110 require that all dairy products that are in final package form and intended for human consumption shall first be pasteurized before they cross state lines. In essence, no person may take raw dairy products across state lines and/or deliver them into interstate commerce if those products are to be consumed by humans. FDA's regulatory program may make sense in the context of the conventional dairy industry in this country, but it makes no sense with respect to Plaintiffs' conduct.

With respect to the conventional dairy industry in this country, the farmer is just the first step in a very long supply chain, with increasing risks at every step. For

example, producers milk their cows, they sell the milk to milk haulers who haul the milk around the country in stainless steel containers, picking up hundreds and thousands of gallons of milk from producers all over the region, mixing and commingling that milk with milk from dozens of other producers, who then sell that milk to processors who process thousands upon thousands of gallons of milk in huge vats, mixing and commingling milk from all over the region (which qualifies them as "milk plants"), pasteurizing the milk so that it can then be sent off to a packaging and labeling facility, where the milk is packaged in containers and then sold to retail grocery stores over wide geographical areas and then ultimately sold to consumers in grocery stores. That is the industrial government sponsored and sanctioned dairy system with which most people are accustomed. In that system, government regulations may be justified to protect the public health and safety.

However, FDA's regulatory program has no application to a private group of citizens who have opted out of the industrial food system and chosen to consume raw dairy products provided to them directly by a farmer, with no commingling or processing, in direct, private transactions. In this case, Plaintiffs have decided they wish to consume their own food of their own choice and have chosen to belong to a group of like-minded individuals that have retained the services of experienced farmers who tend to and manage pasture-based dairy cows. FDA's regulatory program has no application to Plaintiffs' conduct because Plaintiffs are not injuring the public's health, safety or welfare.

If anyone is being harmed in this case it is Plaintiffs themselves because they are being prevented by their government from exercising their fundamental right to consume

the food of their choice and instead are being forced by their government to participate in a food production system that they truly believe is harmful to their health. What is perverse in all of this is that FDA is using Plaintiffs' tax dollars to prevent Plaintiffs from engaging in and exercising their fundamental right to consume food of their own choice.

Plaintiffs have no interest in consuming pasteurized milk that comes from cows injected with artificial hormones and antibiotics that is processed and packaged at large industrial facilities under confinement conditions and then transported hundreds of miles across the country only to sit on store shelves under artificial lighting in plastic bottles and jugs. Instead, Plaintiffs wish to consume fresh, unprocessed, wholesome milk and similar dairy products, and wish to patronize the pasture-based farmers that make these products directly available to the consumer. However, FDA's regulatory program in the form of 1240.61 and 131.110 is preventing Plaintiffs from enjoying their rights to health and food choice. Therefore, this is an issue of private choice, not the public's health, safety or welfare.

FDA, however, seeks to avoid judicial review of its regulations by claiming that the issues are not ripe because it allegedly has not sought to enforce 1240.61 and 131.110. Yet FDA has forced one Plaintiff to destroy raw milk that he and others owned and has threatened enforcement against several other individuals in similar factual and legal positions. FDA's actions have already had consequences for the individual Plaintiffs and for members of the Plaintiff FTCLDF. FDA seeks to shift attention from its own actions to the Plaintiffs by contending that Plaintiffs must first file a "citizens petition." Yet FDA has failed to respond to a citizens petition in violation of the very

procedure it now seeks to invoke. Consequently, this case presents a clear and present dispute for judicial review of agency action.

Accordingly, and as explained below, FDA's motion to dismiss is not well taken and it should be denied.

II. Standard of Review.

On a motion to dismiss under Rule 12(b)(1), "the complaint must be successfully challenged on its face or on the factual truthfulness of its averments." *Med-Tec, Inc. v. Kostich*, (J. Bennett), 980 F. Supp. 1315, 1321 (N.D. Iowa 1997). Thus, there are two types of Rule 12(b)(1) challenges, a factual challenge and a facial challenge. *See Titus v. Sullivan,* 4 F.3d 590, 593 (8th Cir. 1993).

With respect to a facial challenge to subject matter jurisdiction, "all of the factual allegations concerning jurisdiction are presumed to be true." *Id*. at 593. Such a motion is successful only if "the plaintiff fails to allege an element necessary for subject matter jurisdiction." *Id*. With respect to a factual challenge, "the court may receive competent evidence such as affidavits, deposition testimony, and the like in order to determine the factual dispute." *Id*. In a factual challenge situation, the proper course for the movant is to "request an evidentiary hearing on the issue." *Id*.

Moreover, challenges to this Court's jurisdiction "are not restricted to the face of the pleadings." *Wells' Dairy, Inc. v. American Indus. Refrigeration, Inc*., (J. Bennett), 157 F. Supp.2d 1018, 1036 (N.D. Iowa 2001). Consequently, this Court "has the authority to consider matters outside the pleadings on a motion challenging subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1)." *Med-Tec, Inc. v. Kostich*, (J. Bennett), 980 F. Supp. 1315, 1321 (N.D. Iowa 1997). *See also Deuser v. Vecera*, 139

F.3d 1190 (8th Cir. 1998).

In this case, it appears that FDA's motion to dismiss for lack of subject matter jurisdiction combines both a factual challenge and a facial challenge to subject matter jurisdiction. On the one hand, FDA alleges that Plaintiffs have failed to plead the elements necessary for Article III standing, i.e., injury, causation and redressability and thus "cannot make the requisite showing of injury in fact." *See* page 10 of FDA's brief. On the other hand, FDA alleges that even if Plaintiffs demonstrate an injury in fact, "plaintiffs' constitutional claims fail as a matter of law." *See* page 10 of FDA's brief. Consequently, Plaintiffs' allegations in their first amended complaint must be construed as true, all inferences must be resolved in their favor, and the Court is allowed to consider the affidavits submitted by Plaintiffs in support of their argument that they have standing to bring their claims.

With respect to a motion to dismiss under Rule 12(b)(6), "the court must assume all facts alleged in [the complaint as] true, and must liberally construe those allegations." *McFarland v. McFarland*, (J. Bennett), 684 F. Supp.2d 1073, 1078-1079 (N.D. Iowa 2010) (citation and quotation omitted). The complaint "does not need detailed factual allegations" yet it does require "more than labels and conclusions." *Id*. at 1081. The complaint must "contain factual allegations sufficient to 'raise a right to relief above the speculative level….'" *Id*. If the allegations present a claim that is "plausible on its face" then it will defeat a motion to dismiss. *Id*. *See also Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); *Parkhurst v. Tabor,* 569 F.3d 861, 865 (8th Cir. 2009).

As described below in Sections III and IV, Plaintiffs have pled facts sufficient to

defeat FDA's motion in its entirety.

III. Plaintiffs have standing to bring this declaratory judgment action and this Court has subject matter jurisdiction to entertain it.

A. In the context of a declaratory judgment action, a Hobson's choice confers Article III standing.

FDA's arguments on standing go deeply into the merits of Plaintiffs' claims and into FDA's version of what do and do not constitute fundamental rights. But standing does not require that Plaintiffs prove their case. All that standing requires is "enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct]." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 556, 127 Sup. Ct. 1955, 1965 (2007). According to the United States Supreme Court, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" *Id.* (citation omitted). Consequently, this Court has jurisdiction over Plaintiffs' claims if their right to recover "will be sustained if the Constitution and laws of the United States are given one construction and will be defeated if they are given another . . . ." *Steel Co. v. Citizens for Better Environment,* 523 U.S. 83, 89, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998). *See also Verizon Maryland, Inc. v. Public Service Com'n of Maryland,* 535 U.S. 635, 642-643, 122 S.Ct. 1753 (2002).

In this case, Plaintiffs have brought a declaratory judgment action pursuant to 28 U.S.C. 2201(a) which provides, in part, that in "a case of actual controversy within its jurisdiction * * * any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration…." With respect to establishing standing in the context of a declaratory judgment action, injury is not an element because it "[has] no equivalent in the law of

declaratory judgments…." *Steffel v. Thompson*, 415 U.S. 452, 471-472 (1974). Instead, a declaratory judgment action is one of those situations where "Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before…." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 580 (1992) (concurring opinion).

In essence, a declaratory judgment action gives Plaintiffs standing because they have "such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination." *Massachusetts v. E.P.A.*, 549 U.S. 497, 517 (2007). As stated by the Eighth Circuit Court of Appeals, "[w]hen government action ... is challenged by a party who is a target or object of that action, ... 'there is ordinarily little question that the action ... has caused him injury, and that a judgment preventing ... the action will redress it.'" *Monson v. Drug Enforcement Admin*., 589 F.3d 952, 958 (8th Cir. 2009) (citations omitted). *See also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-562 (1992). Consequently, and as the Eighth Circuit Court of Appeals has recognized, when a party "must either make significant changes to [their conduct] to obey [a challenged law], or risk a criminal [or civil] enforcement action by disobeying the regulation," this Hobson's choice confers Article III standing. *Minnesota Citizens Concerned for Life v. Federal Election Com'n*., 113 F.3d 129, 131 (8th Cir. 1997).

As described below, FDA has in fact taken the position that it is illegal for an individual to take raw milk across state lines. In addition, the FDA has taken the position that it is illegal for dairy farmers to make raw milk "available" for distribution across state lines. Thus, and as alleged in the complaint, all of the Plaintiffs are engaged in

allegedly illegal behavior and they are refusing to modify their conduct to satisfy FDA. Instead, all Plaintiffs are willing to be prosecuted by FDA for their conduct because all Plaintiffs believe the "law" that FDA is enforcing is illegal. Thus, all Plaintiffs have Article III standing to bring this action.

1. Under FDA's own interpretation, all Plaintiffs are engaged in conduct that allegedly constitutes a violation 1240.61 and 131.110.

In this case, Plaintiffs have alleged that 1240.61 and 131.110 are unconstitutional as applied to them, that 1240.61 exceeds the authority of FDA as granted to it by the Public Health and Safety Act ("PHSA"), that 131.110 exceeds the authority of FDA as granted to it by the Food, Drug and Cosmetic Act ("FDCA"), and that 1240.61 and 131.110 are arbitrary and capricious. In other words, Plaintiffs believe that 1240.61 and 131.110 are illegal. Consequently, they must either comply with what they believe are illegal laws or they must risk an enforcement action by choosing to ignore them. This gives Plaintiffs standing in the context of a declaratory judgment action.

To demonstrate the likelihood of their probable recovery, this Court may either hold an evidentiary hearing or Plaintiffs may rely "on pleadings and affidavits." *Epps v. Stewart Information Services Corp.*, 327 F. 3d 642, 646 (8th Cir. 2003). *See also Sierra Club v. E.P.A.,* 292 F.3d 895, 900 (D.C. Cir. 2002) (Plaintiffs may establish their standing "by the submission of [their] arguments and any affidavits or other evidence appurtenant thereto at the first appropriate point in the review proceeding."); *Citizens Against Ruining The Environment v. E.P.A*., 535 F.3d 670, 675 (7th Cir. 2008) ("While in many cases a petitioner's standing is self-evident, when it is not, the petitioner must supplement the record to the extent necessary to establish her entitlement to judicial review at the first appropriate point in the proceeding."). Since FDA has not asked for an

evidentiary hearing, Plaintiffs have submitted affidavits in support of their standing. As explained in the affidavits attached hereto, Plaintiffs have more than adequately pled facts to raise a reasonable expectation that they will prevail on their claims if the laws of the United States are construed in a manner that is consistent with their arguments.

The affidavit of Plaintiff Eric Wagoner, a Georgia resident, demonstrates that he was told by an FDA employee to dump out some milk that had been obtained in South Carolina by his agent. *See* Wagoner Affidavit, attached hereto as Exhibit A. Specifically, Wagoner allowed his agent to drive his truck to South Carolina, 110 gallons of raw milk were purchased from a farm in South Carolina (where it is legal to purchase raw dairy products), two gallons of which were owned by Wagoner, and then the agent drove back into Georgia. Wagoner lost the use of his property because he was forced to dump out his raw milk at the order of FDA. A two part video of this activity can be viewed at the You Tube website, part 1 accessible at www.youtube.com/watch?v=EMfQXxVAPgk and part 2 at http://www.youtube.com/watch?v=wPey52Ybp0U. FDA's actions have clearly caused an injury to Wagoner.

The other individual Plaintiffs[7] who drive into neighboring States to legally obtain raw dairy products are similarly "breaking the law" as interpreted by FDA, i.e., if Wagoner was violating 1240.61 by his conduct, so too are all of the other individual Plaintiffs when they drive into neighboring States to legally purchase raw dairy products and then drive back into their State of residence to consume the milk. In other words, the individual Plaintiffs must either refrain from engaging in what they believe is lawful

[7] Laurie Donnelly, Jennifer Allen, Dr. Joseph Heckman, Dane Miller, Cynthia Lee Rose, Anne Cooper.

conduct or they can keep engaging in the conduct that FDA deems unlawful and risk an enforcement action by the FDA. This creates an Article III injury. *See Minnesota Citizens Concerned for Life v. Federal Election Com'n*., 113 F.3d 129, 131 (8th Cir. 1997) (when a party "must either make significant changes to [their conduct] to obey [a challenged law], or risk a criminal [or civil] enforcement action by disobeying the regulation," this Hobson's choice confers Article III standing.). Therefore, all of the individual consumer Plaintiffs have suffered or are suffering an injury- in-fact at the expense of FDA.

With respect to the single farmer Plaintiff in this case, Michael Buck sells raw dairy products in the State of South Carolina where it is legal to do so. *See* Complaint, pars. 40, 41. However, some of his customers are from out of state, for example, Georgia and North Carolina, to which they take their raw dairy products after purchasing them from Buck. *See* Complaint, par. 42. In addition, Plaintiff Buck sells some of his raw dairy, legally, to a store in South Carolina, some of whose customers are out-of-state residents. *Id*. As demonstrated by the affidavits of Pete Kennedy and Steve Bemis, attached hereto as Exhibits B and C, FDA considers this a violation of 1240.61 because Buck would allegedly be "causing to be delivered in interstate commerce" raw dairy products.

Specifically, Kennedy's affidavit shows that dairy farmers in the State of Washington, Michael and Anita Puckett of Dee Creek Farm, were the subjects of a criminal action brought by the United States Department of Justice at the request of the FDA. In the Dee Creek case, residents from Oregon traveled to the Puckett's farm in Washington to obtain raw dairy products. The Pucketts made raw dairy products

available to their shareholders through a herdshare[8], the legitimacy of which was challenged by the Washington authorities.

The Oregon residents obtained raw dairy products from the Pucketts in Washington and then returned to Oregon to consume their milk. The Pucketts were aware their shareholders were Oregon residents. Even though the Pucketts themselves did not ship any milk across state lines, the FDA sent the Pucketts a warning letter informing them they were violating 1240.61. Ultimately, the Pucketts were criminally charged with a misdemeanor for distributing adulterated food in interstate commerce and were sentenced by the Honorable United States Magistrate Judge Karen L. Strombom in October 2008. *See* Case No. 3:08-cr-05424, W.D. Wash.

Moreover, Kennedy's affidavit also shows that FDA has alleged that a dairy farmer in South Carolina, where it is legal to sell raw milk, is also in violation of 1240.61. FDA is claiming that residents in Georgia are operating a "cooperative" and that this cooperative obtains its raw dairy products from the farmer in South Carolina. Specifically, FDA is alleging that this dairy farmer's "raw milk is sold through" the co-op in Georgia. Thus, FDA is alleging this South Carolina dairy farmer has "caused to be delivered in interstate commerce" raw dairy products because he is allegedly causing to be delivered raw dairy products to a state other than South Carolina.

In this case, Plaintiff Buck is doing the same thing as the South Carolina and Washington farmers did, i.e., he is making raw milk available to consumers that includes

[8] A herdshare is an operation where a group of individuals purchase an undivided ownership interest in a herd of cows and the shareholders then board their herd at a dairy farm. This type of arrangement is historically known as an Agistment agreement. Because of their ownership interest in the herd, the shareholders also have an ownership interest in the raw milk and raw dairy products produced by their herd.

out-of-state residents. Consequently, Buck can either continue his conduct and subject himself to a criminal action or he can stop his conduct and comply with what he believes is an illegal regulation. Thus, according to the Eighth Circuit, Buck has standing to bring this action because he "must either make significant changes to [his conduct] to obey [a challenged law], or risk a criminal [or civil] enforcement action by disobeying the regulation." *See Minnesota Citizens Concerned for Life v. Federal Election Com'n*., 113 F.3d 129, 131 (8th Cir. 1997). Consequently, Buck has Article III standing.

Bemis' affidavit demonstrates that FDA has taken the same position in Michigan and in Illinois. Bemis' affidavit shows that Michigan and Illinois residents lease a herd of cows located in Indiana, and that the Indiana farmer tends to, manages and takes care of the herd leased by the Illinois and Michigan residents. Bemis' affidavit also shows that the Indiana farmer would make the raw dairy products produced by the herd available to the Illinois and Michigan residents. FDA informed the Indiana farmer that he was in violation of 1240.61 and 131.110 because he was "delivering in interstate commerce" raw dairy products. Thus, even when a farmer makes raw dairy products available across state lines to individuals who have a leasehold interest in the raw dairy products, FDA takes the position that this conduct violates 1240.61 and 131.110. Moreover, FDA takes this position even though the farmer himself, like Plaintiff Buck in this case, never crosses state lines.

Therefore, all of the Plaintiffs have standing and FDA's motion to dismiss should be denied.

B. Plaintiffs' declaratory judgment action is ripe for review and Ewing is not on point.

FDA makes a curious three-part argument that Plaintiffs lack standing.

Specifically, FDA suggests no injury is occurring because FDA has yet to "enforce" the law against any of the Plaintiffs; this lack of enforcement means that Plaintiffs' action is not "ripe;" and that *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), prevents Plaintiffs from "enjoining" future FDA enforcement. None of these arguments are well taken and each will be addressed separately below.

First, and as described above, FDA has actually taken action against Plaintiff Wagoner, i.e., FDA has ordered him to dump his legally purchased raw milk onto the ground and destroy it. Thus, all Plaintiffs are at risk of having FDA order the destruction of their raw milk as well. Moreover, to argue that Plaintiffs are not violating the law because FDA has not taken any enforcement action against them is to argue that a driver can speed through a residential neighborhood at 75 mph and not be in violation of the posted speed limit unless and until a law enforcement officer writes the driver a ticket.

Furthermore, the Eighth Circuit Court of Appeals has held that a party who is arguing that the law does not apply to them need not wait for enforcement of that regulatory program against them before bringing their action. *See Monson v. Drug Enforcement Admin.*, 589 F.3d 952, 959 (8th Cir. 2009) ("Like the farmer in *New Hampshire Hemp Council,* Monson and Hauge contend that their proposed activities are not governed by the CSA and are outside the reach of the DEA's statutory authority. We agree with the First Circuit, and we conclude that in the circumstances of this case, Monson and Hauge should not be required to apply for registration pursuant to a regulatory scheme that they contend does not apply to their activities in the first place."). Thus, FDA's argument that Plaintiffs lack standing because FDA has not yet taken any enforcement action against them is not well taken and should be rejected.

Second, the existence of an ongoing enforcement action is not required for purposes of standing in a declaratory judgment action. In order to determine whether a declaratory judgment action is "ripe" for review, the Eighth Circuit Court of Appeals has held that the issues should be "largely legal in nature," they can be "resolved without further factual development," and resolution of the case "will largely settle the parties' dispute." *Nebraska Public Power Dist. V. MidAmerican Energy Co*., 234 F.3d 1032, 1038 (8th Cir. 2000). Moreover, a "party need not wait for actual harm to occur." *Id*. *See also Pacific Gas and Elec. Co. v. State energy Resources Conservation & Development Commission*, 461 U.S. 190, 201-202 (1983) ("One does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough."); *Abbott Laboratories v. Gardner*, 387 U.S. 136, 152 (1967) ("This is also a case in which the impact of the regulations upon the petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage.").

In this case, Plaintiffs are being harmed by not being allowed to exercise their fundamental right to travel or to feed themselves and their families the foods of their choice. Either Plaintiffs must refrain from exercising these inalienable rights or they face an enforcement action from FDA. Because all of Plaintiffs' averments in their complaint must be construed as true, this case presents purely legal issues, i.e., are 1240.61 and 131.110 unconstitutional as applied to them. Moreover, the issues should be addressed now to resolve this dispute so that FDA and Plaintiffs can gain clarity on the application, scope and extent of 1240.61 and 131.110. Consequently, the absence of any FDA enforcement action is irrelevant to whether Plaintiffs' declaratory judgment action is ripe

for review.

Third, FDA disingenuously suggests that this case is governed by *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950) and that *Ewing* precludes Plaintiffs' action. Nothing could be further from the truth. Indeed, the United States Supreme Court has already determined that *Ewing* does *not* apply to a declaratory judgment action.

In the case of *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967) *rev'd on other grounds*, FDA had promulgated regulations impacting the prescription drug industry. The new regulations required that "every time" the drug's trade name (e.g., Tylenol) was used in printed material its established name (e.g., acetaminophen) also had to be used in the printed material. Certain drug manufacturers brought a declaratory judgment action against FDA, claiming that the regulations did not apply to them and that for them to immediately comply with what they believed was an illegal requirement would cost them substantial time and money.

In *Abbott*, FDA argued that *Ewing* applied and that the declaratory judgment action should be dismissed. The Supreme Court in *Abbott* did not agree with FDA. The *Abbott* court first considered "whether Congress by the Federal Food, Drug, and Cosmetic Act intended to forbid pre-enforcement review of this sort of regulation promulgated by the Commissioner" (*id*. at 139-140) and concluded that "nothing in the Food, Drug, and Cosmetic Act itself precludes this action." *Id*. at 148. Thus, *Abbott* squarely rejected the argument that FDA is making in this case.

The following demonstrates how disingenuous FDA is being in its motion to dismiss when arguing that this case is controlled by *Ewing*. On page 16 of its motion, FDA alleges that *Abbott* "reaffirmed the *Ewing* principle" and that *Abbott* called *Ewing*

"clearly correct." However, what the *Abbott* court **actually** said about *Ewing* is as follows:

> [*Ewing*] was quite clearly correct, but nothing in its reasoning or holding has any bearing on this declaratory judgment action challenging a promulgated regulation.

Id. at 147.

Moreover, FDA presents only half the loaf on page 16 of its motion when it quotes the following from *Abbott*, alleging that the:

> [drug] manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the [FDCA].

What FDA fails to mention to this Court in its motion is that the *Abbott* court, **in the very next sentence**, said the following:

> That the [*Ewing*] Court refused to permit such an action is hardly authority for cutting off the well-established jurisdiction of the federal courts to hear, in appropriate cases, suits under the Declaratory Judgment Act and the Administrative Procedure Act challenging final agency action of the kind present here. We conclude that nothing in the Food, Drug, and Cosmetic Act itself precludes this action.

Id. at 148.

Thus, the *Abbott* court found that the regulations being challenged by the drug manufacturers were "final agency action" (*id*. at 149) and the impact of the regulations was "sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage." *Id*. at 152. Consequently, the drug manufacturers' declaratory judgment action was "ripe" for review.

Although the *Abbott* court's holding that the Administrative Procedure Act granted federal courts an independent jurisdictional basis to hear challenges to agency

action was subsequently overturned, *Abbott's* reasoning on the ripeness of declaratory judgment actions to "pre-enforcement" review of FDA actions has withstood the test of time and remains to this day the seminal case of the ability to bring a declaratory judgment action to challenge the application of final agency action. *See Pacific Gas and Elec. Co. v. State energy Resources Conservation & Development Commission*, 461 U.S. 190, 201 (1983) ("In *Abbott Laboratories,* which remains our leading discussion of the doctrine, we indicated that the question of ripeness turns on 'the fitness of the issues for judicial decision' and 'the hardship to the parties of withholding court consideration.'").

Accordingly, *Abbott* controls this case. Therefore, FDA's arguments are not well taken and Plaintiffs' declaratory judgment action should proceed.

C. FDA's lack of standing arguments are not persuasive and its cases in support are not on point.

FDA makes several arguments as to why Plaintiffs lack standing, all of which are unpersuasive. However, FDA itself has a "Hobson's choice" to make and it must either fish or cut bait. On the one hand, FDA can admit that 1240.61 and 131.110 *do not* apply to Plaintiffs' conduct, in which case this Court can deny FDA's motion to dismiss and grant Plaintiffs the declaratory relief they seek. On the other hand, FDA can admit that 1240.61 and 131.110 *do* apply to Plaintiffs' conduct, in which case this Court can deny FDA's motion to dismiss because the Plaintiffs would have standing under Article III as explained above in Section III. A and B. Either way, FDA cannot hide behind its motion to dismiss and its argument that Plaintiffs have not suffered an injury in fact because FDA has not taken any enforcement action against any of the Plaintiffs.

FDA also cites to several cases in its motion on the standing issue that are either not on point or are not controlling. For example, FDA cites to *Regenerative Sciences,*

Inc. v. FDA on page 12 of its brief for the proposition that a Hobson's choice is not enough to confer standing and that the mere issuance of a "warning letter" does not confer standing. Not only has that argument been rejected in *Abbott*, the court in *Regenerative Sciences* found that FDA had not taken any "final agency action." Instead, FDA had issued changes to its regulations where "the determination of which regulations and statutes should govern Regenerative's use of HCT/Ps is uncertain at this juncture." *Id*. at *8. Because there was no final agency action, there was no standing. In this case, 1240.61 and 131.110 both constitute final agency action (which as FDA admits on page 14 of its brief have been in existence for 21 and 37 years respectively), the application of which has already been enforced by FDA against farmers and at least one consumer.

On page 12, FDA cites to *Advantage Media, L.L.C. v. City of Eden Prairie*, 456 F.3d 793 (8th Cir. 2006) for the proposition that redressability is lacking in this case because Plaintiffs' conduct would "still violate other unchallenged provisions" of law. Not only does FDA fail to identify the "other laws" that Plaintiffs would allegedly be violating by purchasing raw dairy products in a state where it is legal to do so and then taking those dairy products across state lines so they could be consumed, *Advantage Media* is easily distinguishable.

In *Advantage Media*, the plaintiff brought an action selectively challenging some regulations that regulated the content of billboards. Plaintiff argued that its application for a billboard permit was improperly denied and brought both a facial and an as-applied challenge to the regulations that served as the basis for the denial. The court found that because the plaintiff's billboards would still be in violation of other applicable billboard regulations that were not even the subject of the challenge, the facial challenge was not

appropriate. The as-applied challenge, however, was allowed. "We turn next to Advantage's applied challenges. * * * Advantage's claim is therefore redressable, and it has standing." *Id*. at 802. Thus, even if "other applicable provisions of law" would be violated, which there are none in this case, Plaintiffs' as-applied challenge should go forward.

FDA also argues that even if Plaintiffs obtain a favorable ruling from this Court, such a ruling would "not make sales lawful in Iowa or many other states." That is not the point. Regardless of whether or not raw milk sales are legal or illegal in Iowa or in other states, 1240.61 and 131.110 still prevent, for example, the Iowa Plaintiffs from legally buying raw milk in Nebraska and bringing it back into Iowa. There is no law in Iowa that states "no person shall consume raw milk in Iowa" but both 1240.61 and 131.110 ban bringing raw milk from Nebraska into Iowa even though it is legal in Iowa to consume raw dairy products.

If 1240.61 and 131.110 were found not applicable to Plaintiffs' conduct, the Iowa Plaintiffs would be able to freely enter Nebraska and legally purchase milk in that state, whether or not that purchase was illegal in Iowa, and then legally consume it in Iowa. Consequently, FDA's argument that even if an Iowa Plaintiff prevails in this case they would still be prohibited from buying raw milk in Iowa has no bearing on that Iowa Plaintiff's ability to go into Nebraska and legally purchase raw milk and then consume it in Iowa.

On page 14, FDA argues that Plaintiffs "posit a number of *possible* interpretations of FDA's regulations" that "*could* render" plaintiffs' conduct unlawful (emphasis in original) and that "in the absence of an actual enforcement action" plaintiffs' claims "are

unfit for judicial review." FDA then cites to *National Right to Life Political Action Committee v. Connor*, 323 F.3d 684 (8th Cir. 2003), *Texas v. U.S.* 523 U.S. 296, 118 S.Ct. 1257 (1998), *BBK Tobacco & Foods, LLP v. U.S. Food and Drug Admin*., 672 F.Supp.2d 969 (D. Ariz. 2009) and *Paraquad, Inc. v. St. Louis Housing Authority*, 259 F.3d 956 (8th Cir. 2001) to suggest that because "contingent future events" may or "may not occur at all," Plaintiffs' action is not ripe.

As has already been addressed in Section III. A., FDA's argument is a red herring and lacks merit. Specifically, FDA's regulations force Plaintiffs to choose between two bad options – abandoning their rights or risking enforcement actions – and that is enough to confer Article III standing in a declaratory judgment action. Furthermore, Plaintiffs' allegations must be construed as true, not as a hypothetical. Moreover, and as evidenced by the affidavits of Wagoner, Bemis and Kennedy, FDA has already evinced its interpretation of 1240.61 and 131.110, i.e., Plaintiffs' conduct constitutes a violation of law. Thus, there is nothing "hypothetical" about this case.

Because the Plaintiffs' allegations are based on final regulations adopted by FDA, which is clear "final agency action" for purposes of the APA, causing actual existing injury to the Plaintiffs, the instant case is distinguishable from those cited by FDA. For example, *National Right to Life* dealt with a situation where it was unclear whether or not a fee would be imposed on out-of-state political action committees. "The district court correctly pointed out that '[h]ow the MEC would handle the 'fee' for failing to file prior to the 30 day window would have a significant impact' on our constitutional scrutiny of section 130.011(10).'" *National Right to Life Political Action Committee v. Connor*, 323 F.3d at 693 (8th Cir. 2003). Thus, the case was dismissed for not being ripe because there

was uncertainty whether the filing fee applied. In this case, there is no uncertainty about the Plaintiffs' allegations.

Texas dealt with a situation where the State's School Board had numerous options available to it to address a flagging school district's performance. "When a district fails to satisfy the State's accreditation criteria, the State Commissioner of Education may select from 10 possible sanctions that are listed in ascending order of severity." *Texas v. U.S.* 523 U.S. at 298 (1998). "Whether Texas will [avail itself of the more stringent sanction] is contingent on a number of factors." *Id*. at 300. Thus, the issues were "not fit for adjudication" because the School Board had yet to act and the case was dismissed. *Id*. In this case, both 1240.61 and 131.110 constitute final agency action.

In *BBK Tobacco*, the issue was whether FDA regulations regarding cigarettes applied to tobacco papers or to just the tobacco itself. FDA had issued a "guidance document" that sought to explain FDA's interpretation of whether the regulations applied to the tobacco or to the rolling papers or both. The *BBK Tobacco* court dismissed the case because FDA's guidance document was "not final" and because the issues were not "primarily legal." *BBK Tobacco & Foods, LLP v. U.S. Food and Drug Admin*., 672 F.Supp.2d at 974 (D. Ariz. 2009). According to the court:

> Any action taken against BBK, or any other such company, cannot be premised upon the FDA's guidance documents-regardless of whether the documents are stamped as 'final"' or 'draft.' That is, the FDA's guidance documents do not provide any legal basis from which the FDA can institute civil or criminal legal proceedings. The FDA can only premise such proceedings upon the Tobacco Act itself, or regulations the FDA publishes under the Tobacco Act-*none of which yet exist.*" (Emphasis added).

Id. at 975. In this case, however, 1240.61 and 131.110 are final regulations and the issues presented to this Court are purely legal, i.e., do Plaintiffs have an inalienable right to

cross state lines with raw milk in their possession.

In *Paraquad, Inc. v. St. Louis Housing Authority*, 259 F.3d 956 (8th Cir. 2001), the local housing authority was responsible for constructing a new housing project. Under the terms of the project, the existing residents would be either relocated to the new project (which included units especially designed for the elderly) or the existing residents would be afforded access to other units located elsewhere in the city. An organization representing disabled persons argued that the new project did not include specially designed units for disabled persons as it did for the elderly and thus the disabled were being denied equal protection. The case was dismissed because the *Paraquad* court found that "plaintiffs had not come forward with evidence showing any disabled individuals have been relocated to an inaccessible housing unit, denied relocation at all, or denied public housing" as a result of the new project. *Id*. at 959. Thus, there was no showing of any demonstrated injury.

In this case, however, Plaintiffs have alleged in their complaint that they are being deprived of their inalienable rights to travel across state lines with raw milk in their possession. Because the allegations must be construed as true, Plaintiffs have suffered an injury and therefore have standing. Moreover, FDA's interpretation and application of 1240.61 and 131.110 as demonstrated by the affidavits of Wagoner, Kennedy and Bemis show that Plaintiffs are indeed suffering an injury.

On page 15 of its brief, FDA makes the argument that it has a "strong institutional interest in having this Court withhold review" because if this case proceeds then the floodgates to litigating "hypothetical cases" would be opened. However, the United States Supreme Court in *Abbott* has already rejected this type of argument:

> Finally, the Government urges that to permit resort to the courts in this type of case may delay or impede effective enforcement of the Act. We fully recognize the important public interest served by assuring prompt and unimpeded administration of the Pure Food, Drug, and Cosmetic Act, but we do not find the Government's argument convincing.

Id. at 154. Consequently, FDA must come right out and either admit that Plaintiffs are subject to 1240.61 and 131.110, in which case they are being injured by the prohibitions of 1240.61 and 131.110, or FDA must admit that these regulations do not apply to Plaintiffs' conduct. Either way, this Court should resolve this issue now rather than "withholding review" as FDA suggests.

Moreover, there is no "hypothetical" situation occurring here. As hard as it may be for FDA to believe, Plaintiffs are actually engaging in the conduct they allege in their complaint. Every Plaintiff has chosen for him or herself to defy FDA's categorization of their conduct as "illegal" in an effort to either continue to feed themselves and their families the foods of their choice or, in Plaintiff Buck's case, to make raw milk available to consumers, or face an enforcement action, civil, criminal or otherwise. Thus, the issues presented by this care are purely legal, i.e., do Plaintiffs have the inalienable right to take raw milk across state lines after they have legally purchased it in a neighboring state or, in Plaintiff Buck's case, to make it available for transport across state lines.

Because the issue in this case is whether 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs, this case falls squarely within the ambit of *Abbott* and *Toilet Goods Ass'n. Inc. v. Gardner*, 387 U.S. 158 (1967), wherein the United States Supreme Court stated the following:

> Also, we recognize the force of petitioners' contention that the issue as they have framed it presents a purely legal question: whether the regulation is totally beyond the agency's power under the statute, the type of legal issue that courts have occasionally dealt with without requiring a

specific attempt at enforcement….

Id. at 163. Thus, Plaintiffs do not need to "wait" for FDA to "enforce" the law for this Court to declare whether 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs' conduct.

Finally, FDA argues on pages 16 and 17 that under *Ewing* and its progeny, including *Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980) and *Parke, Davis & Co. v. Califano*, 564 F.2d 1200 (6th Cir. 1977), FDA has the "discretion under the FDCA to initiate a seizure or injunction." While that may be so, this is not a *Ewing*-type situation where Plaintiffs are asking this Court to enjoin FDA from "seizing" their raw milk that they take with them across state lines. Instead, Plaintiffs are asking this Court to declare whether 1240.61 and 131.110, regulations that have been in existence for over 20 years, are unconstitutional as applied to their conduct.

Moreover, the court in *Southeastern Minerals* expressly stated that "[n]o final agency action of the type presented to the Supreme Court in *Abbott Laboratories* is present in the instant case" and thus it was improper to enjoin FDA from seizing product that was regulated by the Food, Drug and Cosmetic Act. *Id*. at 764. In addition, the *Parke, Davis* court expressly stated the following: "In short, this case is controlled by *Ewing v. Mytinger & Casselberry* rather than *Abbott Laboratories v. Gardner*." *Id*. at 1206. Thus, neither *Southeastern Minerals* nor *Parke, Davis* apply to this case.

Consequently, this Court has subject matter jurisdiction over Plaintiffs' claims. Therefore, FDA's argument is not well taken and its motion on the issue of lack of standing should be denied.

IV. Plaintiffs have the inalienable right to consume the foods of their choice for themselves and their families and have thus stated a claim for which relief can be granted.

A. Exhaustion of administrative remedies is a red herring and does not apply to this declaratory judgment action.

Beginning on page 18 of its brief, FDA argues that Plaintiffs have failed to exhaust an alleged administrative remedy and have therefore failed to state a claim. However, a party is not "required to exhaust a remedy which may not exist." *See Parisi v. Davidson*, 405 U.S. 34, 44 (1972). Moreover, the doctrine of exhaustion of administrative remedies does not apply when the agency "lacks institutional competence to resolve the particular type of issue presented, such as the constitutionality of a statute." *McCarthy v. Madigan*, 503 U.S. 140, 147-148 (1992). In addition, exhaustion is not applicable when "the administrative body is shown to be biased or has otherwise predetermined the issue before it." *Id*. at 148. Finally, and assuming an administrative remedy exists, exhaustion is not required when to do so would be an exercise in futility. *See Honig v. Doe*, 484 U.S. 305, 327 (1988) (In a Department of Education action, "parents may bypass the administrative process where exhaustion would be futile or inadequate."). *See also Ace Property and Cas. Ins. Co. v. Federal Crop Ins. Corp.,* 440 F.3d 992, 1000 (8th Cir. 2006); *Van Natta v. Sara Lee Corp*. (J. Bennett), 439 F.Supp.2d 911, 939 (N.D. Iowa 2006) (Exhaustion required under ERISA as long as "there is no showing of futility.")

As explained below, there exists no administrative remedy for Plaintiffs to exhaust; FDA lacks authority to rule on the constitutionality of 1240.61 and 131.110; FDA has already exhibited its bias or predetermination that it will not modify, amend or revoke 1240.61 and/or 131.110; and, assuming an administrative remedy exists in this

case, forcing Plaintiffs to engage in this remedy would be an exercise in futility. Consequently, FDA's exhaustion argument is a not well taken.

To begin, and contrary to FDA's allegations, FDA's regulations at 21 C.F.R. Part 10 do not provide Plaintiffs with an administrative remedy that they need to exhaust. Specifically, 21 C.F.R. 10.25(a) provides, in part, that an interested person may submit a petition to FDA to "*issue, amend, or revoke a regulation* or order, or to take or refrain from taking any other form of *administrative* action." Emphasis added. On its face, this rule does not apply when an entity is challenging the as-applied constitutionality of an administrative regulation through a complaint for declaratory judgment.

Further, 21 C.F.R. 10.30(a) applies only to "any *petition* submitted by a person…." Emphasis added. On its face, this rule does not apply when an entity is challenging the as-applied constitutionality of an administrative regulation through a complaint for declaratory judgment.

Finally, 21 C.F.R. 10.45(a) provides, in part, that it applies to "*final administrative action* taken by the Commissioner…" and 10.45(d) provides, in part, that "the Commissioner's final decision constitutes final agency action." Emphasis added. Examples of "final agency action" would include the Commissioner's issuance of a "generally recognized as safe" designation or the approval or denial of a new drug or medicine. *See, e.g., Garlic v. U.S. Food and Drug Admin.*, 783 F. Supp 4 (D.D.C. 1992) (holding that FDA's denial of an application for a new drug must first be challenged by a citizens petition before resorting to a court of law). On its face, these rules do not apply when an entity is challenging the as-applied constitutionality of an administrative regulation, the application of which FDA lacks any authority to determine.

Therefore, there is no remedy in the Food, Drug and Cosmetic Act that the Plaintiffs need to exhaust before bringing this declaratory judgment action seeking a declaration that 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs.

Not only is an administrative remedy not available in this situation, the doctrine of exhaustion does not even apply in this case. Plaintiffs are bringing an unconstitutional as-applied challenge to 1240.61 and 131.110 yet FDA, as an administrative agency, lacks any authority to rule on the constitutionality of a regulation. See, e.g., *Mathews v. Diaz,* 426 U.S. 67, 76, 96 S.Ct. 1883, 1889, 48 L.Ed.2d 478 (1976). Therefore, the doctrine of exhaustion does not even apply in this case.

Moreover, FDA has already been presented with a citizen's petition asking to amend or rescind 1240.61 and/or 131.110 but has refused to act on it. Indeed, a California raw milk dairy farmer and an organization representing California raw milk consumers co-submitted a citizen's petition to FDA on December 22, 2008. *See* Affidavit of Mark McAfee, attached hereto as Exhibit D. Pursuant to 21 C.F.R. 10.30 (e)(2), FDA had a duty to act on the petition in six months yet as of this date (nearly one year to the date after FDA should have taken action on the petition) FDA has failed to take any action on that petition. Consequently, exhaustion does not apply because FDA has shown itself to be "biased or has otherwise predetermined the issue before it." *McCarthy v. Madigan*, 503 U.S. 140, 148 (1992).

Finally, as demonstrated by the Affidavit of Pete Kennedy, attached hereto, Plaintiffs' requirement to use the citizen's petition process would be an exercise in futility. For example, FDA has issued a statement, stating: "raw milk should not be consumed by anyone, at any time, for any reasons." FDA has also stated the following:

"Drinking raw milk or eating raw milk products is like playing Russian roulette with your health." Indeed, FDA has also recommended to the National Conference on Interstate Milk Shipments that it pass a resolution encouraging States to "pass laws or adopt administrative rules that prohibit the sale of raw milk directly to the household consumer…." *See* Kennedy Affidavit. These public statements clearly show that FDA would not in any way amend or revoke 1240.61 and/or 131.110, or issue a new rule that uses the least stringent means of regulating the interstate distribution of raw dairy products.

FDA has also demonstrated it unwillingness to debate anybody on the issue of raw milk safety. For example, FDA refused to participate in a National Public Radio program on raw milk in 2007, stating that raw milk "is not a debatable issue." Moreover, FDA in 2009 refused to honor its commitment to attend a symposium at the International Association for Food Protection after it learned that a pro-raw milk entity was planning to attend the same symposium. *See* Kennedy Affidavit. Consequently, it would be futile for Plaintiffs to submit a citizen's petition, assuming this remedy is available to them, because FDA has demonstrated its hostility to raw milk.

FDA argues on page 18 of its brief that it has been "prevented [] from developing the factual issues in this matter and applying the agency's own interpretation of its regulations" to the facts alleged in the complaint. That is not true. As explained above in Section III. A. dealing with standing, FDA in 2009 ordered Plaintiff Wagoner to dump his own raw milk onto the ground after it was legally purchased in South Carolina and driven across state lines back to Georgia. And in 2008, FDA criminally charged a Washington state dairy farmer and his wife with distributing an adulterated product in

interstate commerce after they made raw milk available in Washington to residents from Oregon who then took the raw milk across state lines back into Oregon. Consequently, FDA's allegation that it has been prevented from "applying the agency's own interpretation of its regulations" is disingenuous.

FDA presents a novel, circular argument that only "final agency action" can be challenged, and that agency action is final "only after a plaintiff" has exhausted all administrative remedies, i.e., filing a citizens petition.[9] This is indeed a curious argument. In essence, FDA is arguing that before any of its administrative regulations can become "final," a "citizen's petition" must first be filed. Once the citizen's petition has been acted on, FDA can then take "final action." However, 21 C.F.R. 10.45(a) provides that the "citizen's petition" process can be invoked only to challenge "final administrative action." Thus, FDA's argument not only makes no sense, it would turn the notion of administrative rulemaking on its head and should therefore be rejected.

FDA also cites to *Ass'n of Am. Physicians & Surgs., Inc. v. FDA*, 539 F. Supp.2d 4 (D.D.C. 2008) for the proposition that "APA and constitutional claims" should be dismissed under Rule 12(b)(6) when a party neglects to "file a citizen petition as 'mandated' by FDA's regulations.'" However, *Am. Physicians* is not on point.

Am. Physicians involved an FDA administrative determination that a birth control pill (known as "Plan B") was safe for over the counter sales to women aged 18 years and older. FDA's "final administrative action," i.e., Plan B was safe, was challenged by

[9] FDA quotes from *Darby v. Cisneros*, 509 U.S. 137 at page 147 for this proposition yet there is no such language as quoted by FDA on that page in the *Darby* decision. Moreover, *Darby* goes against FDA, the United States Supreme Court stating "Courts are not free to impose an exhaustion requirement as a rule of judicial administration where the agency action has already become 'final.'" *Id*. at 154. In this case, both 1240.61 and 131.110 have been final for over 20 years.

several "right to life" organizations and physicians but it was challenged in court, not via the submission of a citizen's petition. The *Am. Physicians* court stated that although the approval process for Plan B was "a relatively closed process," the citizen petition process provided "an opportunity for interested parties, such as plaintiffs, to participate in the regulatory process." *Id*. at 21. Consequently, the claims brought by the right to life parties were dismissed because "the agency was never provided with an opportunity to address plaintiffs' requests that the FDA take certain actions, such as amending the labeling of Plan B." *Id*.

In this case, Plaintiffs are not seeking to amend, modify or vacate 1240.61 or 131.110. Instead, Plaintiffs are seeking a declaration that these regulations are unconstitutional as applied to their conduct. Therefore, because the remedy Plaintiffs seek is beyond the authority granted to FDA, the citizen petition process is not applicable and FDA's argument that Plaintiffs have failed to exhaust their administrative remedies is a red herring.

Plaintiffs have presented sufficient precedent, argument and facts such that if the allegations in their Complaint are taken to be true they have stated a claim upon which relief may be granted. Therefore, FDA's exhaustion argument is not well taken and its motion should be denied.

B. The right to travel should include the right to have raw dairy products in one's possession.

As FDA admits on page 22 of its brief, 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. 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. *Id*. at 642.

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). 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).[10]

[10] *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

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 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 allege in their complaint and as FDA admits on page 9 of its brief, it is legal to purchase raw milk and/or raw dairy in at least 28 states. 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 go 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 of raw milk and raw dairy products when those products are legally purchased in one state and then taken across state lines to another state where the purchase would be illegal. This constitutes a "classification which serves to penalize the exercise of" the

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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).

fundamental right to travel. *See Shapiro v. Thompson*, 394 U.S. 618, 634 (1969). Consequently, 1240.61 and 131.110 impact the right to travel, for which there is no compelling interest served by these regulations. Because FDA failed to articulate any compelling interest to justify 1240.61 and 131.110, it has waived its right to present any such argument. Nonetheless, even if FDA has not waived it right to prevent a compelling interest behind 1240.61 and 131.110, there is no compelling interest behind 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 purchase of raw milk and/or raw dairy products. For example, Iowa residents (where it is illegal to purchase raw dairy products) can simply travel to Nebraska to legally purchase those products. Thus, 1240.61 and 131.110 do not limit access.

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 purchase 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 raw dairy products. 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.

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 purchase 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."[11] 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 purchase 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 in not served by the multitude of products that can be freely transported across state lines, e.g., knives, hatches, axes, cigarettes, alcohol and medicines. There is no compelling reason why raw dairy products should be prohibited from being taken across state lines yet these other 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. Therefore, 1240.61 and 131.110 constitute an impermissible restriction on the inalienable right to travel.

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[11] 21 CFR 1240.3 defines "communicable diseases" as, in part, "Illnesses due to infectious agents or their toxic products." Raw dairy cannot *per se* be considered a communicable disease unless it contains infectious agents or toxic products.

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

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.

FDA argues on page 22 of its brief that the Constitution does not recognize any "right to travel across state lines *with* unpasteurized milk." Emphasis in original. However, FDA cites to no case law to support its position nor does FDA cite to any authority stating this right *does not* exist. Thus, there is no authority for FDA's proposition that an individual who crosses State lines cannot have raw milk or raw dairy in their possession. FDA simply makes the bald assertion without any authority in support.

On page 23 of its brief, FDA suggests that the United States Supreme Court in *Saenz v. Roe*, 526 U.S. 489, 500-502 (1999), in *dicta*, recognizes *only three* categories of the right to travel and that none of these categories are applicable here. FDA's argument lacks merit and is not true. As the court stated in *Saenz*, "[t]he 'right to travel' discussed in our cases embraces *at least* three different components." *Id*. at 500 (emphasis added).

Saenz stated that at least one of those components is "the right to free interstate movement," *id*. at 501, a right that was recognized in *Edwards v. California*, 314 U.S. 160 (1941) (California law that made it a misdemeanor to bring an "indigent" into California from another state was struck down) and that was subsequently "reaffirmed" on right to travel grounds in *United States v. Guest,* 383 U.S. 745, 86 S.Ct. 1170, 16 L.Ed.2d 239 (1966). *Saenz* did not address this "interstate movement" component of the right to travel; instead, *Saenz* addressed the issue of whether "travelers who elect to become permanent residents" in a new State have "the right to be treated like other citizens of that [new] State." *Id*. at 500. Thus, *Saenz* is not on point because it did not analyze the right to travel component that is present in this case, i.e., the right to free interstate movement.

In this case, this is not a situation where Plaintiffs, from Iowa for example, are asking to be treated like citizens of Nebraska. Rather, Iowa residents are being deprived of their "right to free interstate movement" because 1240.61 and 131.110 are prohibiting them from having raw dairy products in their possession when they cross state lines. Were it not for the existence of 1240.61 and 131.110, Plaintiffs could freely cross state lines with raw dairy in their possession. Thus, *Saenz* is not applicable because Plaintiffs are not asking this Court to be treated like the citizens of other states, rather, they are asking this Court to declare that they have the right to travel across state lines with raw dairy in their possession.

FDA also argues on page 23 of its brief that the "right to travel" jurisprudence of the United States Supreme Court applies only to state laws and cannot be used to attack a federal law. This also is not true. The Supreme Court squarely addressed this issue in

Shapiro, striking down a District of Columbia law impacting the right to travel because it did not promote a compelling governmental interest. *See Shapiro v. Thompson*, 394 U.S. at 642 (1969).

FDA also suggests that the Eighth Circuit in *Minn. Senior Fed'n v. United States*, 273 F.3d 805 (8th Cir. 2001) has rejected the argument that a right to travel claim cannot be used to defeat a federal law, claiming on page 23 of its brief that such an argument is "clearly too broad" because it "finds no support in the Supreme Court's right-to-travel cases." The Eighth Circuit in *Minn. Senior* said nothing of the kind and FDA is misrepresenting to the Court what *Minn. Senior* stated.

In *Minn. Senior*, the issue was whether Minnesota's "Medicare plus choice" program penalized a Florida resident who wished to move to Minnesota because by moving to Minnesota the Floridian would receive less Medicare benefits than she would receive by staying in Florida. The court found that because Minnesota's "Medicare+Choice formula is not affirmatively *penalizing* her right to travel," it concluded that "the right to travel is not implicated by the Medicare+Choice formula and therefore is subject only to rational basis review." *Id*. at 810.

Significantly, the court concluded that "rational basis review is appropriate in considering the constitutionality of federal social welfare programs such as Medicare." Because this was a federal social welfare program subject to rational basis rather than strict scrutiny, the Floridian's argument that "a federal program that fails to achieve nationwide uniformity in the distribution of government benefits is subject to strict scrutiny * * * is clearly too broad" and finds "no support in the Supreme Court's right-to-travel cases." *Id*. Thus, *Minn. Senior* does not stand for the proposition that a right to

travel claim cannot be used to defeat federal law, and FDA should be admonished not to misrepresent the cases it cites in its brief.

Finally, FDA cites to *Doe v. Miller*, 405 F.3d 700 (8th Cir. 2005) for the proposition that recognizing a right to travel "in a situation that does not involve" any of the situations described in *Saenz* would "extend the doctrine beyond the supreme Court's pronouncements in this area." While the proposition may be true, *Doe* did not involve any of the right to travel situations that have been described by the United States Supreme Court.

Instead, *Doe* involved a challenge to a statute that prohibited convicted sex offenders from residing within 2000 feet of a school or a registered child care facility. The court in *Doe* found that the statute "imposes no obstacle to a sex offender's entry into Iowa," there was "free ingress and regress to and from" Iowa, and the statute did not "directly impair the exercise of the right to free interstate movement." *Id*. at 712. The *Doe* court also found that the statute treated residents and non-residents the same, and did not discriminate against residents of other states who wished to visit Iowa. *Id*. Thus, the *Doe* court declined to extend the right to travel doctrine to include the situation argued by the plaintiff in that case.

In this case, 1240.61 and 131.110 *do* impose an obstacle to entry into Iowa when one is in possession of raw dairy products. In fact, it operates as a complete bar on interstate travel when one has raw dairy in one's possession. Therefore, 1240.61 and 131.110 *directly* impair the "right to free interstate movement" as articulated by *Saenz*. *See Saenz v. Roe*, 526 U.S. 489, 501 (1999). Consequently, *Doe* is not on point because Plaintiffs are not asking this Court to expand the doctrine of the right to travel.

The United States Supreme Court's pronouncements in *Shapiro* remain good law and have been cited by subsequent Supreme Court cases in *Soto-Lopez* and in *Saenz*. Thus, 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), *overruled in part on other grounds*. 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. Moreover, 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. *Id*. at 642.

Plaintiffs have presented sufficient precedent, argument and facts such that if the allegations in their Complaint are taken to be true they have stated a claim upon which relief may be granted. Thus, this Court should recognize that the right to travel should include the right to have raw dairy in one's possession.

Consequently, FDA's motion is not well taken and it should be denied.

C. The right to privacy should include the right to feed oneself and one's family the foods of one's choice and to be responsible for one's health.

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/CHAP08.PDF, table 8-16. (Agricultural Statistics 2007, Chapter 8, Dairy and Poultry Statistics).

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 that crosses state lines 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 admits in its brief was promulgated in 1973. Indeed, 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 and does not have any basis in this country's prior 300 year legal heritage.

Moreover, FDA admits that it only became illegal to take raw dairy products across state lines as recently at 1987, the year that 1240.61 was promulgated. Before 1987, it was legal to carry raw dairy products across state lines. Consequently, there is 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 impacts of enzymes, probiotics, and other components that were unknown just a few decades ago. 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.

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[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.

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 have 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 was an issue when they adopted the Constitution, yet FDA is making 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. 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.

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.[14] Nonetheless, as the Constitution endures, "persons in every generation can invoke its principles in their own search for greater freedom." *Id*. at 579. 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.

FDA argues on page 24 of its brief, however, that this Court should exercise "self-restraint" and be "reluctant to expand the concept of substantive due process" and cites to *Doe*, *Glucksberg*, and *Collins v. Harker Heights*, 503 U.S. 115 (1992) in support. None of these cases, however, warrant any caution in this case and they are all easily distinguishable.

In *Doe v. Miller*, 405 F.3d 700 (8th Cir. 2005), the issue was whether an Iowa statute that prohibited sex offenders from residing within 2000 feet of a school or registered child care facility violated the right to travel. The plaintiff in *Doe* argued that this prohibition impacted the substantive due process right of "personal choice regarding the family." The *Doe* court did not accept plaintiff's substantive due process claim because the claim was "so general that it would trigger strict scrutiny of innumerable laws and ordinances that influence 'personal choices' made by families on a daily basis." *Id*. at 710. Thus, *Doe* is not on point because the Plaintiffs in this case are being very specific, i.e., do they have the right to consume the foods of their choice and feed it to their families? Because this is a narrow question, *Doe* does not apply.

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[14] *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.

With respect to *Glucksberg*, the issue was whether a statute that prohibited assisted suicide was consistent with this nation's "history, legal traditions, and practices." *Washington v. Glucksberg*, 521 U.S. 702, 710 (1997). In *Glucksberg*, the Supreme Court reviewed the Anglo-Saxon law, the country's common law, and the nation's statutory law and customs to conclude that this nation has a long and detailed history of prohibiting assisted suicide. Thus, *Glucksberg* does not apply because it merely upheld the country's long standing tradition that assisted suicide was illegal. In this case, however, the requirement that all milk be pasteurized was only recently mandated in 1973, the prohibition against taking raw milk across state lines was only recently mandated in 1987, and for over 300 years it has never been illegal in any state to consume raw dairy products.

With respect to *Collins v. Harker Heights*, 503 U.S. 115 (1992), the issue was whether 14th Amendment substantive due process imposes a duty upon a city to provide its employees with minimal levels of safety and security in the workplace. The *Collins* court found this argument "unprecedented" (*id*. at 127) and held that although the city has a duty to keep citizens safe once they are in the city's custody, it rejected the worker's argument that "the city deprived Collins of his liberty when it made, and he voluntarily accepted, an offer of employment." *Id*. at 128. In this case, there is nothing "unprecedented" in Plaintiffs claim that they have a right to privacy in the form of consuming the raw dairy of their choice. All 50 states allow the consumption of raw dairy and people have been consuming raw dairy since at least the 1600s. Thus, *Collins* is also not on point.

FDA next argues on page 25 of its brief that parents have no "absolute" right to feed their children "any" particular food. Plaintiffs would agree with the following statement: parents do not have the absolute right to feed their children adulterated food. However, it is legal in all 50 states to consume raw dairy products, whether by children or adults. Therefore, it is legal in all 50 states for parents to feed their children raw dairy products.

In addition, it is presumed that parents act in the best interests of their children. *See Parham v. J. R.*, 442 U.S. 584, 604, 99 S.Ct. 2493 (1979). *See also Troxel v. Granville*, 530 U.S. 57, 68 (2000) ("[T]here is a presumption that fit parents act in the best interests of their children."). Moreover, there would "normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children." *Id*. at 68-69. *See also Reno v. Flores,* 507 U.S. 292, 304, 113 S.Ct. 1439, 123 L.Ed.2d 1 (1993). Thus, in the absence of any finding that any of the Plaintiffs in this case are unfit as parents, they have the right to feed their families the foods of their choice without FDA interference.

FDA also argues on page 26 of its brief that there is no "deeply rooted" historical tradition of "unfettered access" to food of all kinds, and that "safety regulation" in this country has "its roots in the early food laws of the American colonies." FDA then cites to the Bible at *Leviticus* 11, 17 and 19, to *Deuteronomy* 14, and to an alleged Virginia statute passed in 1873. Plaintiffs query: where were the pasteurization plants in biblical times? They did not exist. Indeed, people in biblical times drank raw goat, sheep and

cow's milk and consumed raw dairy products as a matter of routine, for thousands of years, long before there was a United States.

Moreover, the alleged 1873 Virginia statute cited by FDA (which Plaintiffs have been unable to locate) addressed a misbranded product, i.e., a product alleged to be milk that had the cream skimmed off the top of it. The alleged 1873 Virginia statute did not operate as an outright ban on access to a particular product nor did it even require pasteurization of dairy products. Thus, the recent "safety regulation" of raw dairy does not have its roots in biblical times nor does it contradict this nation's long history of consuming raw dairy products long before 1873.

Finally, FDA argues that "comprehensive" regulation of the "food supply" has been in effect since 1906. That may be true, but this case does not involve a "comprehensive" regulatory program that deals with the nation's "food supply." Instead, this case involves FDA's authority under the FDCA to regulate foods transported in interstate commerce and whether a person who crosses state lines to obtain raw dairy products and then takes that raw dairy back to their state of residence is engaging in "interstate commerce." Under the facts as alleged in Plaintiffs' complaint, this is not a situation that involves the interstate commerce of food.

To begin, 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 "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). Consequently, the FDCA does not encompass goods that are sold in one state to a consumer, who then takes those goods back to another state. In other words, when an individual goes to one state, purchases raw dairy products in that state, and then takes those products back to his/her own state of residence, that conduct does not constitute "interstate commerce" as that term is defined in the FDCA at 21 U.S.C. 321(b) because the consumer is already protected when he/she purchases a product directly from the producer before the goods are ever shipped 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 regulate the intrastate sales of raw dairy products and has instead left that decision to the several States. Indeed, 21 U.S.C. 331(a) prohibits the distribution of adulterated and misbranded food only in "interstate commerce." 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.

Indeed, 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. 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. 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 analyzed when "interstate commerce" occurs 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* 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.

Moreover, when interstate commerce is not involved, the standard of identity for milk, 131.110, does not apply because FDA's authority under the FDCA exists only with respect to interstate commerce. Consequently, whether or not FDA has been regulating the nation's food supply since the early 1900s, that regulatory program does not offset this nation's history of consuming raw milk and raw dairy products.

In addition, this case involves FDA's authority under the Public Health Safety Act (42 U.S.C. 201, et seq.) to regulate "communicable diseases" from "one State or possession into any other State or possession." *See* 42 U.S.C. 264. A communicable disease is defined as an "illness[] due to infectious agents or their toxic products." 21 C.F.R. 1240.3. However, it defies common sense to define "milk" *per se* as an "illness" for purposes of regulating a "communicable disease." A communicable disease is an *illness*, not an agricultural product that is sold or consumed. In other words, a communicable disease is something like tuberculosis, typhoid, malaria, HIV/AIDS, measles, mumps, rubella, etc. If FDA's argument is accepted, then raw meat, raw chicken, raw eggs or raw produce could be considered a communicable disease.

Moreover, none of the cases cited by FDA in its brief that discusses the substantive due process right to consume the food of one's choice addressed, analyzed or discussed the PHSA. Instead, FDA's cases interpreted the Food, Drug and Cosmetic Act, legislation that does not confer authority on FDA to regulate "communicable diseases." Consequently, there is nothing in the PHSA that can be used as authority to deprive Plaintiffs from consuming the foods of their choice for themselves and their families.

Therefore, this Court should find that Plaintiffs and their families have the right to consume the raw dairy foods of their choice. Accordingly, FDA's motion is not well taken and it should be denied.

With respect to whether Plaintiffs have the right to be responsible for their own health, FDA argues on pages 26-27 of their brief that "courts have consistently refused to extrapolate a generalized right to 'bodily and physical health' from the Supreme Court's narrow substantive due process precedents regarding abortion, intimate relations, and the refusal of lifesaving medical treatment" yet FDA cites to no authority for this bald assertion. Not a single case has been cited by FDA that suggests courts "consistently refuse to extrapolate" a right to bodily and physical health. Had there been such a case or cases, FDA would surely have cited to it or them. FDA's failure to provide any authority for this proposition suggests that its allegation is pure speculation.

Moreover, FDA does not cite to *any* authority that states an individual does *not* have the right to their bodily health. FDA simply makes the bald assertion without any authority in support.

Instead, FDA quotes the following from *Glucksberg*, allegedly on page 721 yet found on page 727 of the court's decision: "many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected." However, there is no such language on page 721 of the *Glucksberg* opinion. Moreover, the simple fact that not "all important, intimate, and personal decisions" are constitutionally protected does not mean that this Case should be dismissed. In any event, the Supreme Court found in *Gluksberg* that abortion, intimate relations and the

refusal of live saving treatment are all rights that are protected by substantive due process yet refused to extend that right to assisted suicide. Thus, FDA's reliance on *Glucksberg* is misplaced.

It is clear that the Supreme Court has recognized the sanctity of an individual's liberty interests in the situations described above on pages 46 and 47. To recognize those liberty interests but deny any interest in one's own health would be an anomaly. Consequently, the right to privacy should include the right to one's health. To suggest otherwise deprives all of us of our basic necessities.

Therefore, FDA's motion to dismiss is not well taken and it should be denied.

V. 1240.61 and 131.110 do not pass either the strict scrutiny or rational basis tests and also exceed the scope of FDA's authority.

With respect to Count One of Plaintiffs' first amended complaint, Plaintiffs argue that 1240.61 and 131.110 do not pass strict scrutiny because they do not promote a compelling governmental interest that is narrowly tailored. As already mentioned in Section III. B., "[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." *See Shapiro v. Thompson*, 394 U.S. 618, 634 (1969)). As explained above in Section III. B., 1240.61 and 131.110 impact the fundamental right to travel and fundamental right to privacy yet fail to pass a strict scrutiny test and are therefore unconstitutional as applied to Plaintiffs' conduct.

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. 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).

For Count Four, 1240.61 and 131.110 exceed FDA's authority because neither the Food, Drug and Cosmetic Act or the Public Health Safety Act give FDA the authority (1) to *completely ban* the interstate transport of raw dairy products; (2) to *completely ban* citizens from traveling across state lines with raw dairy products in their possession because such conduct does not amount to "interstate commerce;" (3) to designate raw dairy products as an "illness" or "communicable disease" *per se*. If there were authority in the PHSA and/or the FDCA that authorizes FDA to *completely ban* the interstate transport of raw dairy products, to completely ban citizens from traveling across state lines with raw dairy products in their possession, or to designate raw dairy products as an "illness" or "communicable disease" *per se*, FDA would have cited to that authority.

FDA's failure to cite to any such authority is telling and is fatal to its argument that 1240.61 and 131.110 are in accordance with their regulatory authority.

In Count Five, the right to contract claim, Plaintiffs assert that if an individual has the right to cross state lines with raw dairy products in their possession it would not be rational to forbid that individual's agent from crossing state lines with raw dairy products in the agent's possession. As the Eighth Circuit has stated, in order to comport with substantive due process, laws must bear a "reasonable relation to a proper legislative purpose, and [must be] neither arbitrary nor discriminatory." *See U.S. v. Buckner*, 894 F.2d 975, 978 (8th Cir. 1990). 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.

In this case, FDA has already taken the position that Plaintiff Wagoner's agent was not allowed to keep the raw dairy in his possession that was taken from South Carolina into Georgia. Thus, it would not be rational to allow Mr. Wagoner to transport raw dairy across state lines yet prevent Mr. Wagoner's agent from doing the same thing.

FDA, however, apparently does not understand Plaintiffs' arguments with respect to Counts One, Four and Five of the first amended complaint. Rather than responding to these arguments, FDA restates and then misrepresents Plaintiffs' arguments.

For example, FDA insinuates on page 19 that Plaintiffs are arguing that nothing in the PHSA or the FDCA authorizes FDA to "promulgate the regulations." That is not true. Plaintiffs are *not* arguing that FDA lacks any authority to "promulgate the regulations." Plaintiffs admit that the PHSA and the FDCA confer rulemaking authority upon FDA. What Plaintiffs are arguing, in part, is that 1240.61 and 131.110 exceed the

scope of FDA's authority.

FDA also suggests on page 20 of its brief that Plaintiffs are claiming that Congress has "impermissibly delegate[d] lawmaking authority" to FDA. That also is not true. Again, Plaintiffs admit that the PHSA and the FDCA confer rulemaking authority upon FDA; those statutes simply do not authorize the type of regulations that took the shape of 1240.61 and 131.110.

FDA also alleges on page 20 of its brief that Plaintiffs failed to argue that the PHSA and/or the FDCA impose "insufficient standards upon FDA." The argument about "insufficient standards" is not the point. The point is, as Plaintiffs alleged in paragraphs 95-98 and 126-129 of their first amended complaint, that:

> There is nothing in the PHSA that authorizes FDA to ban the consumption of unpasteurized dairy products that are purchased in a State where such purchase is legal.
>
> There is nothing in the PHSA that authorizes the FDA to find that a product that is legal to sell in more than half the States and where it is legal to consume in all 50 States should be banned as a "communicable disease" or "illness" particularly when there are other foods in the United States that cause more cases (or more instances and greater severity) of foodborne illness.
>
> There is nothing in the FDCA that authorizes FDA to promulgate a "standard of identity" or "definition" for raw milk that requires all milk for human consumption to first be pasteurized before or after it is taken across State lines lest such milk be deemed "misbranded."
>
> There is nothing in the FDCA that authorizes FDA to prohibit the interstate movement of goods when the goods are purchased by a consumer in one State and then taken across state lines to another State.

FDA also argues on page 21 of its brief that it promulgated 1240.61 and 131.110 "in obedience to explicit statutory mandates." However, as stated before, there are no "explicit" mandates that all raw dairy products *per se* should be deemed an "illness" or a

"communicable disease," or that all interstate transport of raw dairy products should be *completely banned* instead of being regulated. If there were such "explicit" mandates, FDA would have cited to them and quoted them. FDA's failure to do so is telling and demonstrates that such explicit statutory mandates do not exist.

FDA argues on page 21 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). However, FDA did not follow the *Public Citizen* court's mandates.

To begin, the court in *Public Citizen* ordered FDA to promulgate a regulation under the FDCA that addressed the "sale" of raw dairy in interstate commerce. FDA, however, promulgated a regulation under the PHSA 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. Moreover, 1240.61 was promulgated to regulate a "communicable disease" under the PHSA rather than as a standard of identity under the FDCA. Thus, FDA's actions contravened the mandate of the *Public Citizen* court.

FDA argues on page 22 of its brief that 131.110 was promulgated as a standard of identity under "the considerable discretion conferred by Congress." Congress did not intend for FDA to ban any food item in interstate commerce yet 131.110 operates as a *total ban* on the consumption of all raw dairy products that are shipped in interstate commerce, even though it is legal to consume raw dairy products in all 50 states. In addition, the purpose of a standard of identity is to "protect against fraud and misrepresentation." *See Shamrock Farms Co. v. Veneman*, 146 F.3d 1177, 1178 (9th Cir.

1998). However, 131.110 does not operate to "protect against fraud and misrepresentation" but instead operates as a *total ban* on the distribution of raw dairy products in interstate commerce. When raw dairy products are advertised and held out to be raw dairy products, that is not fraudulent.

Finally, FDA argues on pages 27-29 of its brief that rational basis applies, not strict scrutiny. FDA begins this portion of its argument by alleging on page 28 that "FDA's regulations are presumed to be constitutional" and cites to the United States Supreme Court decision of *FCC v. Beach Commc'ns Inc*., 508 U.S. 307, 313 (1993) for the proposition that FDA's regulations "must be upheld . . . if there is any reasonably conceivable state of facts that could provide a rational basis for them." However, as it did with the *Ewing* case, FDA is misrepresenting the *Beach* case to this Court. What the Supreme Court actually said in *Beach* was the following:

> *a statutory classification* that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis *for the classification*. (Emphasis added).

Id. at 313. FDA fails to cite to any authority that administrative regulations, including FDA's own, are entitled to a presumption of constitutionality. Consequently, FDA's regulations are not entitled to any presumption of constitutionality.

FDA then argues that a "least restrictive means" approach is "immaterial under a rational basis review." Again, FDA does not understand Plaintiffs' argument. What Plaintiffs are arguing under rational basis is that it does not make sense to allow an individual to cross state lines with raw dairy in their possession yet prohibit the agent of the person from crossing state lines with raw dairy in the agent's possession. Under

rational basis, Plaintiffs are *not* arguing least restrictive means. What Plaintiffs are arguing under "least stringent means" is that because 1240.61 and 131.110 both implicate a fundamental right, the least restrictive means must be employed and thus a warning label or some other less intrusive means should be applied to 1240.61 and 131.110. Otherwise, 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs' conduct.

Therefore, 1240.61 and 131.110 exceed the authority granted to FDA by Congress under both the PHSA and the FDCA, either under a strict scrutiny, rational basis, or arbitrary and capricious standard. Accordingly, its motion to dismiss is not well taken and it should be denied.

VI. Conclusion.

All of the allegations in the first amended complaint must be construed as true. Because FDA has not presented any evidence in this case at this point, Plaintiffs' complaint presents purely legal issues that, in the context of a declaratory judgment, confer standing on all the Plaintiffs. Moreover, Plaintiffs' affidavits in support demonstrate that they have standing to bring their claims.

The right to travel should include the right to cross state lines with raw dairy products in one's possession. Because 1240.61 and 131.110 operate as a direct impediment to the fundamental right to travel, they should be struck down as applied to Plaintiffs' conduct.

The right to privacy should also include the right to consume for oneself and one's family raw dairy products. Because raw dairy products have been consumed since the inception of this nation's history, and only as recently as 1973 has pasteurization been imposed at the federal level and as recently as 1987 has traveling across state lines with

raw dairy in one's possession been illegal, 1240.61 and 131.110 should be struck down as applied to Plaintiffs' conduct.

The right to privacy should also include the right to one's health. Because our other fundamental rights would be meaningless if we were not healthy, 1240.61 and 131.110 should be struck down as applied to Plaintiffs' conduct.

Raw dairy products cannot be considered a "communicable disease" *per se* nor can they be considered "untruthful and misleading" *per se*. Whether analyzed under a rational basis, strict scrutiny or arbitrary and capricious standard, 1240.61 and 131.110 exceed the scope of authority granted to FDA by Congress under either the PHSA and/or the FDCA.

Finally, interstate commerce does not encompass an individual traveling from one state into another to make a purchase and then take the purchased product back to the person's state of residence.

For these reasons, FDA's motion to dismiss should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2010, 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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