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

FARM-TO-CONSUMER LEGAL DEFENSE FUND, LAURIE DONNELLY, JENNIFER ALLEN, DR. JOSEPH HECKMAN, DANE MILLER, CYNTHEA LEE ROSE, ERIC WAGONER, ANNE COOPER, and MICHAEL BUCK,

Plaintiffs,

vs.

KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration, and UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants.

No. C 10-4018-MWB

MEMORANDUM OPINION AND ORDER REGARDING DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION AND FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

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Got [raw] milk? This lawsuit presents the interesting question of the validity of Food and Drug Administration (FDA) regulations requiring "milk" in final package form for beverage use to be pasteurized or ultrapasteurized and prohibiting the delivery into interstate commerce of any milk in final package form for direct human consumption unless the product has been pasteurized. The plaintiffs are individuals who purchase "raw" (unpasteurized) milk for their personal consumption in states where the sale of raw milk is allowed, then transport the raw milk to states where the sale of raw milk is not allowed to consume it; the owner of a "virtual farmers' market," who transports raw milk ordered by market members from a state where the sale of raw milk is allowed to a state where the sale of raw milk is not allowed and distributes the raw milk to the members who ordered it; a farmer who sells raw milk, some of which is purchased by people living in other states in which the sale of raw milk is prohibited; and an organization representing the interests of such persons. The plaintiffs challenge the validity of the regulations on the various grounds, including that the regulations violate the plaintiffs' constitutional rights to travel and privacy. The immediate issues, however, raised in the defendants' motion to dismiss, are whether the plaintiffs have standing to assert their challenges to the regulations, whether their claims are ripe for judicial determination, whether the plaintiffs improperly bypassed administrative remedies before filing suit, and whether they state claims upon which relief can be granted.

I. INTRODUCTION

A. Factual Background

Because this matter is before the court on a motion to dismiss, the factual background is drawn primarily from the plaintiffs' Amended Complaint (docket no. 8). This statement of facts is supplemented, where appropriate, on a challenge to the court's

subject matter jurisdiction, by facts drawn from affidavits in support of the plaintiffs' resistance to the defendants' motion to dismiss.

The court will describe six of the individual plaintiffs—Laurie Donnelly, Jennifer Allen, Dr. Joseph Heckman, Dane Miller, Cynthia Lee Rose, and Eric Wagoner, to the extent that his claims rely on the same conduct—as the "direct purchaser plaintiffs." All of the direct purchaser plaintiffs, with the exception of plaintiff Miller, allege that they reside in states where it is illegal to sell raw (unpasteurized) milk, even though it is legal to consume raw milk in those states.[1] They allege, further, that on one or more occasions, they each traveled to an adjacent state where it is legal to sell raw milk in final package form, at least under certain conditions, and legally purchased and obtained such raw milk. They allege that they then traveled back to their home states where they and/or their family members consumed the raw milk. Thus, these plaintiffs each were citizens of "no raw milk sales" states, bought raw milk in adjacent "raw milk sales" states, then took it home to consume in their "no raw milk sales" states. Each alleges that such conduct continues to this day.

Plaintiff Miller's allegations are somewhat different. Plaintiff Miller alleges that he is a citizen of Pennsylvania, where it is legal to sell raw milk, at least under certain conditions, but that he has relatives in Virginia, where it is not legal to sell raw milk. He alleges that, on more than one occasion, he drove from Virginia back to his home state of Pennsylvania, where he legally purchased and obtained raw milk in final package form from a licensed dairy farm. He alleges that he then traveled back to Virginia, in

[1] Plaintiff Donnelly alleges that she resides in Woodbury County, Iowa, which is in the Northern District of Iowa. Plaintiff Allen alleges that she resides in Council Bluffs, Iowa, which is in the Southern District of Iowa. The other individual plaintiffs allege that they reside in states other than Iowa.

possession of the raw milk, where he and his relatives then consumed the raw milk. Thus, Miller is a citizen of a "raw milk sales" state, but he still traveled from a "no raw milk sales" state to a "raw milk sales" state to buy raw milk, then took it back to the "no raw milk sales" state to consume it. Miller also alleges that this activity continues to this day.

The allegations of two of the individual plaintiffs, Eric Wagoner and Anne Cooper, whom the court will describe as the "principal and agent plaintiffs," are different. In addition to his "direct purchaser" allegations, plaintiff Wagoner alleges that he is the owner of an internet-based "virtual farmers' market" based in Georgia that others may join by paying an annual membership fee. He alleges that it is illegal to sell raw dairy products in Georgia, but it is legal to sell them in South Carolina. He alleges that members of his virtual farmers' market residing in Georgia, including plaintiff Anne Cooper and himself, order raw milk in final package form for personal consumption from three dairies located in South Carolina who list their dairy products with the virtual farmers' market. Wagoner alleges that he drives to South Carolina to pick up the raw dairy products, returns with them to Georgia, and distributes them to the members of the virtual farmers' market who ordered them. Wagoner and Cooper allege that Wagoner was Cooper's agent to pick up the raw milk that she had ordered in South Carolina and to deliver it to her in Georgia. Wagoner alleges that the members pay the farmers for the products listed on the virtual farmers' market.

Wagoner alleges that, on October 15, 2009, he was driving from South Carolina to Georgia with about 110 gallons of raw milk in final package form ordered by members of his virtual farmers' market, but upon reaching Georgia, his truck was searched and seized and the raw milk in it was embargoed, without a warrant, by officials from Georgia. He alleges that, on October 19, 2009, he was ordered to and did destroy the 110 gallons of raw milk, including milk "owned" by himself and Cooper, by order of Georgia officials

and the FDA, again without a warrant or other legal process.[2] The FDA counters that allegations that it ordered the destruction of the milk are "bizarre" and unsupported, because if the FDA, rather than state officials, had actually ordered the destruction of the milk as alleged, the FDA would have done so in an *in rem* seizure action, pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 334, in which Wagoner would have had the opportunity to appear and object, but there is no evidence of any such action. The FDA does not offer any affidavits to counter Wagoner's version of these events, however, and apparently does not deny that a FDA agent was present at the destruction of Wagoner's load of raw milk.

Plaintiff Michael Buck, whom the court will describe as the "producer plaintiff," alleges that he owns and operates a dairy farm in South Carolina that is licensed by the State of South Carolina. He also alleges that he has held a retail raw milk license from the State of South Carolina since 2006. He alleges that it is legal to sell raw milk in South Carolina as long as the seller is either a licensed dairy farm or a licensed retail store. Buck alleges that approximately 25% of his milk is sold in South Carolina as retail raw milk. He alleges that he sells only raw milk, and no other raw dairy products, on his farm and to four retail stores in South Carolina. Buck alleges that he has personal knowledge that people from North Carolina and Georgia, where it is illegal to sell raw milk for human consumption, purchase raw milk at his farm and at one or more of the retail stores where he sells his raw milk. Buck alleges that he has never had any sanctions or penalties levied against his dairy; he has never had to dump even a single load of milk since he has been

[2] In the plaintiffs' brief in response to the defendants' motion to dismiss, the plaintiffs advised the court that a two-part video of the destruction of the raw milk on October 19, 2009, can be viewed at www.youtube.com/watch?v=EMfQXxVAPgk and www.youtube.com/watch?v=wPey52Ybp0U.

in business; and, as far as he knows, there has never been any illness caused by the consumption of raw milk produced at his dairy.

Plaintiff Farm-to-Consumer Legal Defense Fund (the "Fund" or "FTCLDF") alleges that it is a non-profit organization organized under the laws of the State of Ohio, with its principal place of business in Falls Church, Virginia. The Fund alleges that it consists of over 1,900 members from 49 different states. The Fund alleges that it is dedicated to protecting and promoting sustainable, environmentally sound farming practices and direct farm-to-consumer transactions, which the Fund believes further the common good and general welfare of all Americans. The Fund alleges that it defends and protects the right of farmers to directly provide, and for consumers to directly obtain, unprocessed and processed farm foods. Toward this end, the Fund alleges that it provides advocacy, education, and legal services for farmers and consumers against any local, state, and federal government interference with the legal transfer of products produced and processed on the farm. Plaintiffs Dr. Joseph Heckman, Eric Wagoner, and Michael Buck allege that they are members of the Fund.

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

All of the plaintiffs also allege that they are, have been, and will be damaged and have suffered, are suffering, and will suffer an injury in fact by the prohibitions contained

in regulations promulgated by the FDA, 21 C.F.R. §§ 1240.61 and 131.110, pursuant to the Food, Drug, and Cosmetics Act (FDCA) and the Public Health Service Act (PHSA). Section 1240.61 provides, in pertinent part, as follows:

> **§ 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.**
>
> (a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

21 C.F.R. § 1240.61(a). Section 131.110 provides, in pertinent part, as follows:

> **§ 131.110 Milk.**
>
> (a) Description. Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 1/4 percent milk solids not fat and not less than 3 1/4 percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

All of the plaintiffs allege that these regulations deprive them of the following fundamental and inalienable rights: (a) the right to travel across state lines with raw dairy products legally obtained and possessed; (b) the right to provide for the care and well being of

themselves and their families, including their children; and (c) the right to produce, obtain, and consume the foods of choice for themselves and their families, including their children. The plaintiffs allege that they are also suffering injury from the promulgation and enforcement of regulations that are beyond the defendants' authority, arbitrary, and capricious.

B. Procedural Background

The plaintiffs filed a Complaint (docket no. 2) initiating this action for declaratory and injunctive relief on February 20, 2010, and an Amended Complaint (docket no. 8) on March 18, 2010. In the Amended Complaint, the plaintiffs named as defendants Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services (HHS), the HHS itself, Margaret Hamburg, in her official capacity as Commissioner of the United States Food and Drug Administration (FDA), and the FDA itself.[3] The plaintiffs assert the following five claims in their Amended Complaint:

First, **Count One** is a claim for declaratory and injunctive relief pursuant to 5 U.S.C. §§ 702 and 706 of the Administrative Procedures Act (APA), alleging that

[3]The plaintiffs allege that venue lies in this district under 28 U.S.C. § 1391(e)(2), because this action involves an agency of the United States as a defendant, because plaintiff Laurie Donnelly resides in this district, and because no real property is involved in this action. Based on these allegations, it appears that the plaintiffs actually relied on § 1391(e)(3) for venue, because that provision provides for venue for a civil action against these federal government defendants in any judicial district in which "the plaintiff resides if no real property is involved in the action." In contrast, § 1391(e)(2), the provision cited by the plaintiffs, provides for venue in an action against these defendants in any judicial district in which "a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated." The defendants do not challenge venue in their motion to dismiss, however.

§§ 1240.61 and 131.110 exceed the FDA's statutory authority and are arbitrary and capricious. Somewhat more specifically, in this Count, the plaintiffs allege that § 1240.61 exceeds the authority of the provision of the Public Health Service Act (PHSA) pursuant to which it was promulgated, 42 U.S.C. § 264(a), which authorizes the making and enforcement of regulations that are "necessary to prevent the introduction, transmission, or spread of communicable diseases . . . from one State or possession into any other State or possession." They also allege that § 131.110 exceeds the authority of the provision of the Food, Drug, and Cosmetic Act (FDCA) pursuant to which it was promulgated, 21 U.S.C. § 343(g), which provides that foods are "misbranded" unless the food conforms to the applicable definition and standard established by regulation. The plaintiffs allege that, when read together, § 1240.61 and § 131.110 prohibit a citizen from traveling to a neighboring state to legally obtain raw milk and/or raw dairy products (other than exempted raw cheese aged sixty days or more) in final package form, *e.g.*, in a bottle or carton, and taking those products back into a state where sales of raw dairy products are not allowed, unless the milk and/or dairy products have first been pasteurized, even if they obtained the milk for their own personal consumption. They allege, further, that § 1240.61 and § 131.110 prohibit farmers who legally sell raw milk and/or raw dairy products (other than exempted raw cheese aged sixty days or more) in their state in final package form, *e.g.*, in a bottle or carton, from selling those products to consumers from another state, who then take them back into their own states for their own personal consumption, unless the milk and/or dairy products have been pasteurized before they are sold to the out-of-state consumers. The plaintiffs also allege that nothing in the PHSA authorizes the FDA to ban the consumption of unpasteurized dairy products that are purchased in a state where such purchase is legal; nothing in the PHSA authorizes the FDA to find that a product that is legal to sell in more than half the States and legal to consume

in all 50 States should be banned as a "communicable disease" or "illness" particularly when there are other foods in the United States that cause more cases of food-borne illness; that nothing in the FDCA authorizes the FDA to promulgate a "standard of identity" or "definition" for 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"; and that nothing in the FDCA authorizes the 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.

Count Two is also a claim for declaratory and injunctive relief, pursuant to 5 U.S.C. §§ 702 and 706, alleging that § 1240.61 and § 131.110 violate the plaintiffs' fundamental constitutional right to travel. Somewhat more specifically, in this Count, the plaintiffs allege that they have a fundamental right to travel from one state to another state in a manner free from unnecessary burdens, but that, because § 1240.61 and § 131.110 effectively ban the interstate movement or distribution of raw milk and raw milk products in final package form for human consumption, those regulations, as applied, violate their constitutional right to travel. The plaintiffs allege that there are effective, but less restrictive means of regulating the interstate movement or distribution of raw milk and raw dairy products in the possession of people intending to consume them or in the possession of their agents, such as allowing interstate movement of raw dairy products, if they were produced in compliance with the laws of the originating state, or they bear appropriate warning labels. The plaintiffs also allege that the defendants do not have a compelling interest in protecting individuals from traveling across state lines while in possession of raw milk and/or raw dairy products, because individuals are capable of choosing for themselves which foods to eat.

Count Three is a claim for declaratory and injunctive relief, also pursuant to 5 U.S.C. §§ 702 and 706, alleging that § 1240.61 and § 131.110 violate the plaintiffs' fundamental constitutional right to privacy. Somewhat more specifically, in this Count, the plaintiffs allege that the fundamental right to privacy includes the fundamental right to raise one's family and to be responsible for the care and custody of one's children, and the right to be free from governmental interference with one's bodily and physical health. They also allege that they have a fundamental right to raise their family in their own way, and to their own bodily and physical health, which rights include the right to determine what foods they do and do not choose to consume for themselves and their families. They allege that § 1240.61 and § 131.110 violate these fundamental privacy rights and substantive due process privacy rights.

Count Four is a claim for declaratory and injunctive relief, also pursuant to 5 U.S.C. §§ 702 and 706, alleging that § 1240.61 and § 131.110 violate the non-delegation doctrine recognized by Article 1, Section 1 of the United States Constitution. Somewhat more specifically, in this Count, the plaintiffs allege that the rule-making power granted to administrative agencies is not the power to make law, but to adopt regulations to carry into effect the will of Congress, the body with the power to make law, as expressed by statute. They allege that there is nothing in the PHSA that authorizes the FDA to ban the consumption of unpasteurized dairy products that are purchased in a state where such purchase is legal or to find that a product that is legal to sell in more than half the states and is legal to consume in all 50 states should be banned as a "communicable disease" or "illness" particularly when there are other foods in the United States that cause more instances and greater severity of food-borne illness. They allege, further, that there is nothing in the FDCA that authorizes FDA to promulgate a "standard of identity" or "definition" for milk that requires all milk for human consumption to be pasteurized before

or after it is taken across state lines lest such milk be deemed "misbranded" or to prohibit the interstate movement of goods when the goods are legally purchased by a consumer in one state and then taken across state lines to another state. They allege that only Congress, not the FDA, has the authority to enact legislation that restricts the personal liberty of persons who wish to consume raw milk and raw dairy products by traveling into another State to obtain those products.

Finally, **Count Five** is a claim for declaratory and injunctive relief pursuant to 5 U.S.C. §§ 702 and 706, alleging that § 1240.60 and § 131.110 violate the substantive due process right established by the Fifth Amendment to the United States Constitution. Somewhat more specifically, in this Count, the plaintiffs allege that § 1240.61 and § 131.110 serve no legitimate federal interest in preventing plaintiff Cooper from receiving raw milk and dairy products from her agent or in preventing plaintiff Buck from legally selling raw milk in final package form in his state, where it is legal to do so, to residents from another state where it is not legal to sell raw milk. The plaintiffs also allege that § 1240.61 and § 131.110 serve no legitimate federal interest in prohibiting raw milk from being transported across state lines by an agent, when those products were legally purchased in accordance with state law and when the principal has enlisted the services of an agent to have the principal's own goods delivered to the principal by his or her own agent, or by a consumer who legally purchases raw milk in a state where it is legal to do so from a producer such as plaintiff Buck. Thus, they contend that § 1240.61 and § 131.110 irrationally restrict the use of an agent to accomplish what the principal herself ought to be free to do, and restrict the legal sale of raw milk from a producer in one state to an out-of-state consumer who takes that milk back to the out-of-state person's state of residence, in violation of the Fifth Amendment right to substantive due process.

In addition to declaratory relief, the plaintiffs seek injunctive relief. Specifically, they pray that the court will enjoin any further enforcement—civil, criminal, administrative, or otherwise—of 21 C.F.R. § 1240.61 and 21 C.F.R. § 131.110 against the plaintiffs or anyone else who wishes to distribute or take across state lines raw milk and/or raw dairy products in final package form for personal consumption. They also pray that the court will enjoin the defendants from spending or receiving federal, state, or local taxpayer funds on any activity related to enforcement of 21 C.F.R. § 1240.61 and 21 C.F.R. § 131.110. Finally, the plaintiffs seek attorney fees, costs, and all other relief that the court deems just and reasonable.

On April 26, 2010, the defendants filed a pre-answer Motion To Dismiss (docket no. 10), seeking dismissal of the Amended Complaint for lack of subject matter jurisdiction and failure to state claims upon which relief can be granted, pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. On June 15, 2010, the plaintiffs filed a Resistance To Defendants' Motion To Dismiss (docket no. 17), with four affidavits attached. On April 21, 2010, the defendants filed a Reply (docket no. 19) in further support of their Motion To Dismiss.

The court heard oral arguments on the defendants' Motion To Dismiss on July 22, 2010. At the oral arguments, the plaintiffs were represented by David G. Cox in Columbus, Ohio, and Wallace L. Taylor in Cedar Rapids, Iowa, and the defendants were represented by Roger Gural and Jennifer Zachary, Trial Attorneys, Office of Consumer Litigation, Department of Justice, Civil Division, in Washington, D.C., Martha Fagg, Assistant United States Attorney, in Sioux City, Iowa, and Larry Kudje, Assistant United States Attorney, in Cedar Rapids, Iowa.

On July 24, 2010, two days after the oral arguments, the plaintiffs filed a Motion To Admit Newly Discovered Evidence (docket no. 24). The evidence in question consists

of e-mails exchanged between a reporter for the Iowa Public Radio Network and a press officer for the FDA and e-mails thereafter exchanged between counsel for the parties. The defendants filed a Resistance To Plaintiffs' Motion To Admit Newly [Discovered] Evidence (docket no. 25) on July 30, 2010, and the plaintiffs filed a Reply (docket no. 26) in further support of their motion that same day.

Both the defendants' Motion To Dismiss and the plaintiffs' Motion To Admit Newly Discovered Evidence are now fully submitted.

II. LEGAL ANALYSIS

A. Subject Matter Jurisdiction

In the portion of their Motion To Dismiss seeking dismissal pursuant to Rule 12(b)(1), the defendants assert that this court lacks subject matter jurisdiction over this action, because the plaintiffs do not have standing, their claims are not ripe for review, and their claims for declaratory and injunctive relief barring the government from applying the FDA's regulations to the plaintiffs are foreclosed by *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). The plaintiffs resist dismissal on these grounds.

1. Justiciability requirements

As the Eighth Circuit Court of Appeals recently explained,

> "Federal courts are not courts of general jurisdiction; they have only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto." *Bender v. Williamsport Area Sch. Dist.,* 475 U.S. 534, 541, 106 S. Ct. 1326, 89 L. Ed. 2d 501 (1986). "The limitations imposed by Article III are usually referred to as the 'case or controversy' requirement." *Schanou v. Lancaster County Sch. Dist. No. 160,* 62 F.3d 1040, 1042 (8th Cir. 1995) (quoting *Arkansas AFL-CIO v. FCC,* 11 F.3d 1430, 1435 (8th Cir. 1993) (en banc)); *see also Valley Forge*

> *Christian College v. Americans United for Separation of Church & State, Inc.,* 454 U.S. 464, 471, 102 S. Ct. 752, 70 L. Ed. 2d 700 (1982) ("Article III of the Constitution limits the 'judicial power' of the United States to the resolution of 'cases' and 'controversies.'"). This court defines "case or controversy" to require "a definite and concrete controversy involving adverse legal interests at every stage in the litigation." *McFarlin v. Newport Special Sch. Dist.,* 980 F.2d 1208, 1210 (8th Cir. 1992). "Federal courts must always satisfy themselves that this requirement has been met before reaching the merits of a case." [*Schanou,* 62 F.3d at 1042.]

Gray v. City of Valley Park, Mo., 567 F.3d 976, 982-83 (8th Cir. 2009).

The Eighth Circuit Court of Appeals has also explained that "'[c]ourts employ a number of doctrines to determine justiciability [for subject matter jurisdiction purposes] such as standing, ripeness, and mootness.'" *Gray*, 567 F.3d at 983 (quoting *Schanou,* 62 F.3d at 1042). The defendants' challenges to the court's subject matter jurisdiction here rest on two of these justiciability doctrines, standing and ripeness. "[I]f a plaintiff lacks standing, the district court has no subject matter jurisdiction." *Id.* at 981 (internal quotation marks and citations omitted). Similarly, "[t]he issue of ripeness, which has both Article III and prudential components, is one of subject matter jurisdiction." *Dakota, Minnesota & Eastern Railroad Corp. v. South Dakota*, 362 F.3d 512, 520 (8th Cir. 2004). "A Rule 12(b)(1) motion challenges whether the district court has subject matter jurisdiction to hear the matter." *Johnson v. United States*, 534 F.3d 958, 964 (8th Cir. 2008). The court will consider the defendants' challenges to subject matter jurisdiction under the standing and ripeness doctrines in turn.

2. Nature of the defendants' challenge

Before considering the defendants' standing and ripeness challenges, however, the court must determine what, if anything, beyond the Amended Complaint it should consider

to resolve those challenges. The specific question is whether the court should consider either the affidavits offered by the plaintiffs in support of their resistance to the defendants' Motion To Dismiss or the evidence identified in the plaintiffs' Motion To Admit Newly Discovered Evidence.[4]

That question turns on whether the defendants' present challenge to subject matter jurisdiction under Rule 12(b)(1) is facial or factual. On a facial attack, the court must accept all factual allegations in the pleadings as true and view them in the light most

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[4]More specifically, the plaintiffs attached to their Resistance To Defendants' Motion To Dismiss (docket no. 17) an affidavit of plaintiff Eric Wagoner concerning the incident in which he was ordered to destroy raw milk that he was transporting from South Carolina to Georgia to distribute to members of his virtual farmers' market, *see* Resistance, Exhibit A; an affidavit from Peter Kennedy, an attorney and the current president of the plaintiff Fund, concerning his personal knowledge of enforcement actions by the FDA against persons purportedly similarly situated to some of the plaintiffs in this action, *see id.*, Exhibit B; an affidavit from Stephen Bemis, an attorney and member of the plaintiff Fund, concerning his personal knowledge of other enforcement actions by the FDA against other persons purportedly similarly situated to some of the plaintiffs in this action, *see id.*, Exhibit C; and an affidavit of Mark McAfee, who alleges that the FDA subjected him to enforcement action for conduct similar to that alleged by plaintiff Buck in this action, *see id.*, Exhibit D. In their July 24, 2010, Motion To Admit Newly Discovered Evidence (docket no. 24), the plaintiffs seek to supplement the record with various e-mails between a reporter for the Iowa Public Radio Network and a person in the FDA press office, exchanged in May and early June, 2010, and received by plaintiffs' counsel on June 15, 2010, *see* plaintiffs' Motion To Admit Newly Discovered Evidence, Exhibit 1; a June 16, 2010, e-mail from plaintiffs' counsel to defendants' counsel, requesting a conference call to discuss how best to present this "newly discovered evidence" to the court, *see id.*, Exhibit 2; a June 24, 2010, e-mail from plaintiffs' counsel to defendants' counsel forwarding the e-mails in Exhibit 1, *see id.*, Exhibit 3; and a June 24, 2010, e-mail from defendants' counsel forwarding to plaintiffs' counsel an e-mail from the FDA press officer to the Iowa Public Radio Network reporter, which stated, *inter alia*, that the press officer's interpretation of the law in his earlier e-mails to the reporter "was totally incorrect" and referred the reporter to "the government brief in [this] case," *see id.*, Exhibit 4.

favorable to the non-moving party. *Hastings v. Wilson*, 516 F.3d 1055, 1058 (8th Cir. 2008); *see also United States v. Metropolitan St. Louis Sewer Dist.*, 569 F.3d 829, 834 (8th Cir. 2009) (when a party seeks to dismiss a suit for lack of standing, the court "'must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party,'" quoting *Warth v. Seldin*, 422 U.S. 490, 501 (1975)). On the other hand, when jurisdictional facts are in dispute, "[t]rial courts have 'wide discretion to allow affidavits, other documents, and a limited evidentiary hearing to resolve disputed jurisdictional facts under Rule 12(b)(1).'" *Johnson v. United States*, 534 F.3d 958, 964 (8th Cir. 2008) (quoting *Holt v. United States*, 46 F.3d 1000, 1003 (10th Cir. 1995)); *see also Precision Press, Inc. v. MLP U.S.A., Inc.*, 620 F. Supp. 2d 981, 986-88 (N.D. Iowa 2009) (discussing, in detail, the differences between a facial and a factual challenge to subject matter jurisdiction). As this court has also noted, the proper course for a factual challenge is for the defendant to request an evidentiary hearing on the jurisdictional issue, so that the court can determine the matter, not simply rule on whether there is or is not enough evidence to have a trial on the issue. *Precision Press*, 620 F. Supp. 2d at 988 (citing *Osborn v. United States*, 918 F.2d 724, 730 (8th Cir. 1990)).

It is not altogether clear whether the defendants are mounting a facial or factual attack on subject matter jurisdiction. On the one hand, the defendants appear to challenge plaintiff Wagoner's allegations about the involvement of the FDA in the destruction of the raw milk that he transported from South Carolina to Georgia for members of his virtual farmers' market, as well as all of the plaintiffs' allegations that enforcement action by the FDA against them or similarly situated persons has occurred or is likely to occur. On the other hand, the defendants submitted no affidavits or other evidence to attempt to contradict the plaintiffs' jurisdictional allegations, and made no request for an evidentiary hearing. What is clear is that the defendants want the court to take their factual assertions

in their brief as true, with no hearing and no evidentiary support, but not take the plaintiffs' factual allegations in their Amended Complaint as true nor consider the plaintiffs' affidavits and other evidence offered in support of their contentions that this court has subject matter jurisdiction.

The court finds that the ambiguous nature of the defendants' challenge to subject matter jurisdiction warrants considering, in the first instance, for whatever value it may have, the evidence offered by the plaintiffs in support of their resistance to the defendants' challenge to subject matter jurisdiction, including both the affidavits with their original resistance and the evidence submitted with their Motion To Admit Newly Discovered Evidence. *Cf. Johnson*, 534 F.3d at 964 (where the defendant makes a factual challenge to subject matter jurisdiction, the court has wide discretion to determine how to determine how to resolve disputed jurisdictional facts); *see also Precision Press*, 620 F. Supp. 2d at 988 (in the absence of a request for an evidentiary hearing, the court considered the matters outside the complaint offered by the parties). At the same time, the court concludes that doing so does not mean that the court is necessarily making a "final" determination of the plaintiffs' standing or the ripeness of their claims at this time, when an evidentiary hearing or a summary judgment motion on a more complete record may demonstrate clearly whether the plaintiffs do or do not have standing and whether or not their claims are ripe for review. *Precision Press*, 620 F. Supp. 2d at 987 (in the absence of a request for an evidentiary hearing and a clear factual attack on subject matter jurisdiction, the court will only dismiss a complaint for lack of subject matter jurisdiction, if it appears beyond doubt that the plaintiff cannot prove jurisdictional facts in support of the plaintiff's claims). In other words, while the court will consider the plaintiffs' proffered evidence, in light of the defendants' failure to plainly assert a factual challenge

or to request an evidentiary hearing, the court will construe the defendants' present challenge to subject matter jurisdiction to be only a facial challenge.

The court's willingness to consider the plaintiffs' evidence, including their "newly discovered evidence," does not mean that the court is convinced that there is good cause for the plaintiffs' failure to supplement their response to the defendants' Motion To Dismiss with their purportedly "newly discovered evidence" prior to the oral arguments on the Motion To Dismiss or to offer their purportedly "newly discovered evidence" at the oral arguments. The plaintiffs admit that they came into possession of the "new" evidence before the oral arguments. Thus, their assertion that there was no way that they could have presented this evidence to the court except via a motion to admit new evidence after the oral arguments rings hallow. Instead, their conduct in reserving some evidence until after the court took the matter under advisement looks like gamesmanship. However, the court does not find that the defendants will be prejudiced by the court's consideration of the belatedly offered evidence, because it has little, if any, probative value on any question presented here, where the plaintiffs have made no showing that the FDA employee, identified by the defendants as a "press officer," involved in the e-mail exchanges with the public radio reporter had any policy-making authority or any authority to interpret regulations.

With the questions of what record the court will consider and how final the court's determination of subject matter jurisdiction will be at this point resolved, the court turns to consideration of the defendants' challenge to the plaintiffs' standing and the ripeness of their claims.

3. Standing

a. Arguments of the parties

The defendants assert that the plaintiffs cannot make the required showing of injury in fact to establish their standing, because their constitutional claims fail as a matter of law. Moreover, the defendants contend that the plaintiffs cannot show any real or immediate threat that the FDA will institute an enforcement action against them, because they have not pointed to a single enforcement action by the government against others similarly situated, that is, individuals buying unpasteurized milk for personal consumption or retailers of unpasteurized milk purportedly not engaging in interstate commerce, nor do they allege that the FDA has in any way signaled an intention to enforce the challenged regulations against any of the plaintiffs. The defendants point out that they have not issued warning letters to any of the plaintiffs, notifying them that they are potential targets of enforcement actions, but even such a warning letter does not confer standing on a recipient, because such letters do not commit the FDA to enforcement action. The defendants contend that the plaintiffs point only to a purported "Hobson's choice," between modifying their behavior to comply with the regulations or facing potential enforcement for violating the regulations, but there is no threat of future injury sufficient to create such a "Hobson's choice" to establish standing in this case. Finally, the defendants assert that the plaintiffs are without standing, because there is no causal connection between their alleged injury and the FDA's regulations, and a favorable ruling from this court will not remedy their alleged injury. This is so, the defendants contend, because unpasteurized milk is unavailable in the states where the plaintiffs live, so that a ruling that the FDA's interstate commerce regulations may not be applied to the plaintiffs would not make sales of raw milk lawful in those states.

In response, the plaintiffs contend that they do not have to prove the merits of their claims to prove standing, they must only allege enough facts to raise a reasonable expectation that discovery will reveal evidence of illegal conduct. Moreover, they contend that, in the context of a declaratory judgment action, injury is not an element of standing. They contend that a declaratory judgment action gives them standing, because they have sufficient personal stake in the outcome of the controversy to assure adverse views are presented. They contend that the "Hobson's choice" that they face is sufficient to convey standing, because the Eighth Circuit Court of Appeals recognized in *Minnesota Citizens Concerned for Life v. Federal Election Commission*, 113 F.3d 129, 131 (8th Cir. 1997), that a party has standing when he or she must either make significant changes to his or her conduct to obey a challenged law, or risk criminal or civil enforcement action by disobeying the regulation. The plaintiffs assert that the FDA has, in fact, taken the position that it is illegal for an individual to take raw milk across state lines and for dairy farmers to make raw milk available for distribution across state lines. Thus, they contend that they have alleged that they are engaged in allegedly illegal behavior and are refusing to modify their conduct to satisfy the FDA. They point specifically to the affidavit of Eric Wagoner concerning the incident in which he alleges that he was required by the FDA to dump raw milk that he had transported from South Carolina to Georgia. They assert that, if Wagoner was violating the regulations at issue, so too are all of the other individual plaintiffs when they legally obtain raw milk in neighboring states and transport it back to their home states. They contend that affidavits from counsel representing persons who are not parties here demonstrate that the FDA also considers it a violation of the regulations for a farmer, like plaintiff Buck, to make raw dairy products available in a state where it is legal to do so, if he knows that some of his customers take those raw dairy products across state lines.

In their Reply in further support of their motion, the defendants contend that nothing in the plaintiffs' resistance shows that they have standing to bring this action. Indeed, the defendants contend that the plaintiffs are unabashedly asking for an advisory opinion from this court, even though they have steadfastly refused to use the FDA's citizen's petition process to obtain an advisory opinion from the agency. They also contend that the Eighth Circuit Court of Appeals has rejected the notion that a declaratory judgment action gives a plaintiff standing, because the Declaratory Judgment Act creates only a remedy, not a right of entry into the federal courts.

b. Analysis

As the Eighth Circuit Court of Appeals has explained,

> Article III standing represents "perhaps the most important" of all jurisdictional requirements. *FW/PBS,* 493 U.S. at 231, 110 S. Ct. 596. This doctrine "requires federal courts to satisfy themselves that the plaintiff has alleged such a personal stake in the outcome of the controversy as to warrant [her] invocation of federal-court jurisdiction." *Summers v. Earth Island Inst.,* --- U.S. ----, 129 S. Ct. 1142, 1149, 173 L. Ed. 2d 1 (2009) (internal quotations and emphasis omitted). In the normal course, the plaintiff has the responsibility clearly to allege facts demonstrating that she is a proper party to invoke judicial resolution of the dispute and the exercise of the court's remedial powers. *Warth v. Seldin,* 422 U.S. 490, 518, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975). This assures the existence of that measure of concrete adverseness necessary to sharpen the presentation of issues necessary for the proper resolution of the constitutional questions. *City of Los Angeles v. Lyons,* 461 U.S. 95, 101, 103 S. Ct. 1660, 75 L. Ed. 2d 675 (1983).
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> To satisfy Article III's standing requirement, (1) there must be "injury in fact" or the threat of "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not

> conjectural or hypothetical; (2) the injury must be fairly traceable to defendant's challenged action; and (3) it must be likely (as opposed to merely speculative) that a favorable judicial decision will prevent or redress the injury. *Summers,* 129 S. Ct. at 1149; *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.,* 528 U.S. 167, 180-81, 120 S. Ct. 693, 145 L. Ed. 2d 610 (2000). The standing "requirement assures that 'there is a real need to exercise the power of judicial review in order to protect the interests of the complaining party.'" *Summers,* 129 S. Ct. at 1149 (quoting *Schlesinger v. Reservists Comm. to Stop the War,* 418 U.S. 208, 221, 94 S. Ct. 2925, 41 L. Ed. 2d 706 (1974)). To determine whether a pre-enforcement challenge such as this is justiciable requires us to take these factors into consideration on a case-by-case basis. *Regional Rail Reorganization Act Cases,* 419 U.S. 102, 143 n. 29, 95 S. Ct. 335, 42 L. Ed. 2d 320 (1974).

Gray, 567 F.3d at 983-84; *see also True v. Nebraska*, ___ F.3d ___, ___, 2010 WL 2696744, *1 (8th Cir. July 9, 2010) (describing the requirements for standing as "(1) an injury in fact, (2) a causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury is redressable by a favorable decision").

The gravamen of the "injury in fact" requirement for constitutional standing, at the motion to dismiss stage, is whether the plaintiffs have "asserted facts that affirmatively and plausibly suggest that they are indeed subject to a credible threat of prosecution under the [regulation] for engaging in conduct for which they invoke constitutional protection." *Zanders v. Swanson*, 573 F.3d 591, 594 (8th Cir. 2009). "While general factual allegations of injury might suffice to establish standing in some instances, general allegations of *possible* or *potential* injury do not." *Id.* (emphasis in the original). The plaintiffs must "'nudge[] their claims across the line from conceivable to plausible.'" *Id.* (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Claims that are too

conjectural or hypothetical are insufficient to support the exercise of the court's jurisdiction. *Id.* at 594-95 & n.3.

More specifically, plaintiffs have standing to challenge the *facial* validity of a regulation notwithstanding the pre-enforcement nature of a lawsuit, where the impact of the regulation is direct and immediate and they allege an actual, well-founded fear that the law will be enforced against them. *Gray*, 567 F.3d at 984. Thus, a plaintiff has standing to assert a *facial* challenge to the validity of a regulation or statute, even in the absences of a specific threat of enforcement, if the court need neither speculate nor attempt to anticipate whether that plaintiff will fall within the purview of the regulation, and the plaintiff alleges an intention to engage in a course of conduct that is clearly proscribed by statute. *Id.* In such circumstances, the presence of the regulation is threat enough. *Id.* at 986. The bar is not so high to show standing to assert a pre-enforcement *as applied* challenge to a regulation or statute, however. Although subjective apprehensions of enforcement are still not enough, *see, e.g., Morrison v. Board of Educ. of Boyd County*, 521 F.3d 602, 610 (6th Cir. 2008), a plaintiff asserting a pre-enforcement *as applied* challenge need only demonstrate that a "credible threat of an injury exists," and may do so by showing (1) that the plaintiff was threatened with prosecution; (2) prosecution is likely; or (3) there is a credible threat of prosecution. *See, e.g, American Charities for Reasonable Fundraising Regulation, Inc. v. Pinellas County*, 221 F.3d 1211, 1214 (11th Cir. 2000).

Injury is "fairly traceable" to the government conduct or regulation in question when there is an alleged causal connection between the government's conduct or regulation and the plaintiff's injury. *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 592 (8th Cir. 2009). Moreover, "'[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) (quoting *Minnesota Citizens Concerned for Life v. Federal Election Comm'n*, 113 F.3d 129, 131 (8th Cir. 1997), in turn quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992), with alterations by the *Monson* court).

i. Standing of the direct purchaser plaintiffs. The six individual plaintiffs that the court has identified as the "direct purchaser plaintiffs"—Laurie Donnelly, Jennifer Allen, Dr. Joseph Heckman, Dane Miller, Cynthia Lee Rose, and Eric Wagoner, to the extent that his claim is based on the same conduct—allege that they purchased raw milk in a state where such purchases were allowed, then transported the raw milk to states where such purchases are not allowed to consume it or to give it to friends or family members to consume. The court finds that it is a very close question whether these plaintiffs have standing to assert a pre-enforcement *as applied* challenge to the regulations in question. On the present record, however, taking their allegations as true, and noting the defendants' failure to offer contrary evidence, the court finds that these plaintiffs have made a preliminary showing that a "credible threat of an injury exists" from possible enforcement of the regulations against them. *American Charities for Reasonable Fundraising Regulation, Inc.*, 221 F.3d at 1214. This is so, because it is plausible to read "cause to be delivered into interstate commerce" within the meaning of § 1240.61 to apply to someone who purchased raw milk in one state, then transported it across state lines for purposes of personal consumption, and it is plausible to read "otherwise distribute [raw milk] after shipment in interstate commerce" within the meaning of § 1240.61 to apply to someone who transported raw milk across state lines, then fed it to other family members or friends. *See Zanders*, 573 F.3d at 594 (the plaintiffs must nudge their claim across the line from the conceivable to the plausible).

More specifically, a provision of the FDCA, 21 U.S.C. § 321(b), defines "interstate commerce" to mean "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body." Courts have interpreted the purpose behind the FDCA's interstate commerce regulation to be to "safeguard the consumer from the time the food is introduced into the channels of interstate commerce to the point that it is delivered to the ultimate consumer." *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92 (1964); *see also United States v. Sullivan*, 332 U.S. 689, 696 (1948) (the provisions 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").[5] In other contexts, "interstate commerce" has been recognized to mean nothing more than persons, products, or contraband crossing state lines. *See, e.g.*, *Carr v. United States*, ___ U.S. ___, ___, 130 S. Ct. 2229, 2237 (2010) (a person traveled in interstate commerce, for purposes of the Sex Offender Registration and Notification Act (SORNA), 18 U.S.C. § 2250(a), if the person crossed state lines); *United States v. Schmidt*, 571 F.3d 743, 747 (8th Cir. 2009)

[5]The court notes that the "general definitions" regulation for "Subpart A—General Provisions" of Part 1240 of the pertinent regulations does not define "interstate commerce" or "delivered" or "cause to be delivered into interstate commerce." *See* 21 C.F.R. § 1240.3. Although that regulation does define "interstate traffic," *see* 21 C.F.R. § 1240.3(h), that term appears in a regulation pertaining to "molluscan shellfish," 21 C.F.R. § 1240.60, not in the regulation pertaining to "milk," 21 C.F.R. § 1240.61. The court declines to read "interstate traffic" to be synonymous with "interstate commerce" absent any indication that the court should do so, where the difference in the choice of language used in the two regulations must be deemed to have some significance. Thus, nothing in the regulatory definitions broadens or narrows the "interstate commerce" language used in § 1240.61 beyond the scope of the statutory "interstate commerce" provisions.

(evidence that a firearm was manufactured in one state or foreign country before coming into a defendant's possession in another state was sufficient to show that the firearm was used in or affected interstate commerce within the meaning of 18 U.S.C. § 922(g)). Thus, the purchase of raw milk by one who traveled between states to obtain it, then traveled between states before consuming it or sharing it with friends or family members, plausibly implicates "commerce between any State . . . and any place outside thereof," *see* 21 U.S.C. § 321(b), "introduction of [raw milk] into the channels of interstate commerce" before delivery to an ultimate consumer, *see Wiesenfeld Warehouse Co.*, 376 U.S. at 92, and "the interstate flow of goods" prior to delivery to an ultimate consumer, *see Sullivan*, 332 U.S. at 696. In short, such conduct plausibly involves "causing [raw milk] to be delivered into interstate commerce." 21 C.F.R. § 1240.61.

Moreover, courts have recognized that there are circumstances in which intrastate activities so affect interstate commerce that they fall within Congress's power to regulate interstate commerce. *See, e.g., Katzenbach v. McClung*, 379 U.S. 294, 301-05 (1964). Thus, while the actual purchases by the direct purchaser plaintiffs were "intrastate," their travel across state lines to make such purchases, and their return with such products across state lines, may nevertheless have involved or have had sufficient effect on interstate commerce to fall within the "interstate commerce" element of § 1240.61.

The court also notes that, in the context of prohibitions on illegal drugs, the Eighth Circuit Court of Appeals has held that "[d]istribution under 21 U.S.C. § 841(a)(1) includes not only the sale of a controlled substance but also the non-commercial transfer from one person to another." *United States v. Basewell*, 792 F.2d 755, 760 n.7 (8th Cir. 1986). Thus, by analogy, "distribution" of raw dairy products under § 1240.61 can also plausibly be read to include transfer to another person, such as a family member, and such a distribution has occurred "after shipment in interstate commerce," where the raw dairy

product was purchased out-of-state, and transported into the state by the purchaser to share with friends or family members.

The direct purchaser plaintiffs also contend that the FDA's direction that plaintiff Wagoner destroy the raw milk that he had purchased for himself, along with all of the other raw milk that he was transporting from South Carolina to Georgia for distribution to members of his virtual farmers' market, demonstrates that there is not only a credible threat that the FDA will enforce the regulations against a direct purchaser plaintiff, but that the FDA has actually done so. On the present record, the court must take as true the plaintiffs' allegations that Wagoner was told to destroy the raw milk that he was transporting across state lines for himself, *because* he had purchased it for himself, as well as the raw milk that he was transporting across state lines to distribute to others. The FDA has made no attempt to present *evidence* that it neither ordered Wagoner to destroy the raw milk, state officials did, nor ordered Wagoner to destroy the raw milk because he was attempting to transport some of the raw milk across state lines for his own consumption.

Thus, on the present record, the direct purchaser plaintiffs have made sufficient showing that they face a credible threat of injury to have standing.

Contrary to the defendants' contentions, these plaintiff's standing also is not defeated by a lack of causal connection between their alleged injury and the regulation or the unlikelihood that a favorable result will redress that injury. *See Gray*, 567 F.3d at 984 (further requirements for standing). When government action is challenged by a party who is a target or object of the government's action or regulation—as is the case here for direct purchaser plaintiffs, where their conduct is plausibly proscribed by the regulation—not only is there ordinarily little question that the government's action or regulation has caused that person injury, but little question that the judicial action will redress it. *Monson*, 589 F.3d at 958. The FDA's argument to the contrary misses the point. The fact that

unpasteurized milk cannot be sold in the states where these plaintiffs live, so that even in the absence of the federal regulations, sales of raw milk would be unlawful in their states, is irrelevant: A declaration that the federal regulations in question are invalid would allow these plaintiffs lawfully to obtain raw milk *from another state*.

Thus, on the present record, taking the direct purchaser plaintiffs' allegations as true, they do have standing.

ii. Standing of the principal and agent. The standing of the "principal and agent plaintiffs," Anne Cooper and Eric Wagoner, to the extent that Wagoner's standing is also based on conduct involving his "virtual farmers' market," depends upon different circumstances. The defendants have largely ignored the difference in circumstances between these plaintiffs and the direct purchaser plaintiffs.

It is more than plausible, *see Zanders*, 573 F.3d at 594 (the plaintiffs must nudge their claim across the line from the conceivable to the plausible), it is likely and reasonable, to read the regulations in question as proscribing a principal (Cooper) from using an agent (Wagoner) to obtain raw milk out-of-state and to deliver it to the principal in the principal's home state, as Anne Cooper has allegedly done. Such conduct is plausibly proscribed by the prohibition on "caus[ing] [raw milk] to be delivered into interstate commerce," *see* 21 C.F.R. § 1240.61(a), where the principal and agent not only had a commercial relationship, but that relationship involves the interstate purchase and distribution of a good or commodity. Similarly, the conduct of the agent (Wagoner) is plausibly proscribed by the prohibition on "otherwise distribut[ing], or hold[ing] for sale or other distribution after shipment in interstate commerce any [raw milk]." *See* 21 C.F.R. § 1240.61(a). Wagoner alleges that he transports raw milk in interstate commerce, in that he transports the raw milk across state lines and delivers it to the members of his virtual farmers' market, pursuant to a commercial transaction.

These plaintiffs' standing also is not defeated by the defendants' contentions of a lack of causal connection between their alleged injury and the regulation or the unlikelihood that a favorable result will redress that injury. *See Gray*, 567 F.3d at 984 (further requirements for standing). When government action is challenged by a party who is a target or object of the government's action or regulation—as is the case here for plaintiffs Cooper and Wagoner, where their conduct is not only plausibly, but clearly proscribed by the regulation—not only is there ordinarily little question that the government's action or regulation has caused that person injury, but little question that the judicial action will redress it. *Monson*, 589 F.3d at 958. Again, the FDA's argument that, even in the absence of the federal regulations, sales of raw milk would be unlawful in their state, is irrelevant: A declaration that the federal regulations in question are invalid would allow these plaintiffs to obtain raw milk *from another state*.

Thus, the principal and agent plaintiffs do have standing.

iii. The producer plaintiff. The standing of the producer plaintiff, Michael Buck, depends upon yet another set of circumstances. Buck alleges that he owns a dairy in South Carolina, that he is licensed to and does sell raw milk on his farm and in retail stores in South Carolina, where it is legal to do so if one possesses a license, but he knows that some of the purchasers of his raw milk at his farm and in the retail stores come from out of state. Again, the defendants have largely ignored the differences between Buck's circumstances and those of the other plaintiffs.

Plaintiff Buck has made a preliminary showing that a "credible threat of an injury exists" from possible enforcement of the regulations against him. *American Charities for Reasonable Fundraising Regulation, Inc.*, 221 F.3d at 1214. It is plausible to read the regulations in question to proscribe a producer, such as Buck, from selling raw milk in an *intrastate* transaction to purchasers from out of state. *See Zanders*, 573 F.3d at 594 (the

plaintiffs must nudge their claim across the line from the conceivable to the plausible). Such a producer may plausibly be construed to have "cause[d] [raw milk] to be delivered into interstate commerce." 21 C.F.R. § 1240.61(a); *see also Gray*, 567 F.3d at 984-95 (the plaintiff has standing if his or her conduct is clearly proscribed by the government regulation); *Wiesenfeld Warehouse Co.*, 376 U.S. at 92 (the purpose behind the FDCA's interstate commerce regulation is 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"). Even though the producer engaged in only intrastate transactions, he plausibly delivered or caused raw milk to be delivered into interstate commerce, when he made intrastate sales to persons he knew were traveling from out of state to purchase the raw milk, then returning with it to their home states to consume it. This is so, again, because there are circumstances in which intrastate activities so affect interstate commerce that they fall within Congress's power to regulate interstate commerce. *See, e.g., Katzenbach*, 379 U.S. at 301-05.

Moreover, Buck has made an adequate preliminary showing that the FDA has enforced the regulation against other allegedly similarly-situated persons to show that there is a credible threat of prosecution against him.[6] *See, e.g, American Charities for*

[6]This is so, notwithstanding that the court finds two of the cases of alleged actual enforcement cited by Buck to be clearly distinguishable. The FDA's warning letter to one producer warned of possible enforcement action for a violation of 42 U.S.C. § 271(a) and 21 C.F.R. § 1240.61(a), based on the producers' distribution of raw milk and cream produced in Indiana, in final package form for direct human consumption, to cooperatives in Michigan and Illinois for further distribution to the cooperative members. *See* Plaintiffs' Resistance (docket no. 17), Exhibit C, Affidavit of Bemis, Attachment A. Similarly, the FDA sent a warning letter to a producer in South Carolina warning of possible enforcement action, again for a violation of 42 U.S.C. §§ 264(a) and 271(a) and (continued…)

Reasonable Fundraising Regulation, Inc., 221 F.3d at 1214. In one of the incidents of alleged enforcement of the regulations against producers, according to a FDA warning letter, an investigation of the producers was apparently prompted by an outbreak of food-borne illness, but the producers were ultimately warned of possible enforcement action based on a FDA inspection that had determined that their dairy farm caused to be delivered into interstate commerce unpasteurized milk, in finished form for human consumption, and that doing so was a violation of the PHSA, 42 U.S.C. § 271(a), and 21 C.F.R. § 1240.61(a). *See* Plaintiffs' Resistance, Exhibit B, Affidavit of Kennedy, Attachment A.[7] There is no indication in the warning letter whether the warning was based on the producer's intrastate or interstate sales of raw milk, even though the *E. coli* outbreak

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[6](…continued)
21 C.F.R. § 1261.40, based on the sale of the producer's raw milk through raw milk "co-ops" in Georgia. *See id.*, Exhibit B, Kennedy Affidavit, Attachment B. In both cases, the producers had unquestionably "cause[d] [raw milk] to be delivered into interstate commerce," because they had engaged in interstate commercial transactions to deliver raw milk to out-of-state entities that engaged in further commercial distribution of the raw milk. In Buck's case, however, his actual sales occurred intrastate.

[7]Although the defendants attempt to distinguish this enforcement action on the basis that the raw milk was contaminated with *E. coli*, that contamination was not identified as the basis for the warning of enforcement for violations of § 1240.61. *Id.* The defendants also assert that courts have "consistently" found that merely receiving a warning letter does not confer standing, because such letters do not commit the FDA to enforcement action, citing *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983), and *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1504 (D. Kan. 1992), and that Buck has not even received such a warning letter. Neither decision stands for the cited proposition, because the court in each case considered "ripeness," a separate principle of subject matter jurisdiction from "standing." *See Biotics Research Corp.*, 710 F.2d at 1376 & 1378; *Clinical Reference Lab., Inc.*, 791 F. Supp. 1503-04. The court will consider, below, whether the fact that Buck has not even received a warning letter demonstrates that his claim is not "ripe."

occurred across state lines. The affidavit of the attorney who represented the producers in question, however, avers that the criminal prosecution of the producers for a violation of 21 C.F.R. § 1240.61 was based on the producers' knowledge that residents of Oregon had traveled to Washington to obtain raw milk from the producers, then had taken the raw milk back across state lines into Oregon for human consumption. *See id.*, Affidavit of Kennedy, ¶ 11. Buck expressly alleges that he also knows that some buyers of his raw milk are from out of state and that they take the raw milk back to their own states for human consumption. *See* Amended Complaint, ¶ 42. Thus, evidence of this enforcement action is sufficient to make a preliminary showing that Buck faces a credible threat of injury, and, therefore, has standing. Again, the defendants' assertions that Buck cannot show the necessary causal connection between his alleged injury and the regulations or that a favorable result will redress that injury, *see Gray*, 567 F.3d at 984 (further requirements for standing), are completely unpersuasive.

Thus, Buck, the producer plaintiff, also has standing.

c. Summary

That part of the defendants' Motion To Dismiss seeking dismissal of the plaintiffs' claims for lack of standing will be denied.[8]

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[8]The defendants do not separately challenge the standing of the "organizational" or "associational" plaintiff, the Fund. Suffice it to say that the Fund has standing, because it has shown, through specific facts, that at least one of its members—indeed, two, Wagoner and Buck—would be directly affected by the challenged regulations, *see Summers v. Earth Island Institute*, 129 S. Ct. 1142, 1151-52 (2009); *Warth v. Seldin*, 422 U.S. 490, 511 (1975), and the claims of those members are germane to the organization's purpose. *Metropolitan St. Louis Sewer Dist.*, 569 F.3d at 834; *see also Americans United for Separation of Church and State v. Prison Fellowship Ministries, Inc.*, 509 F.3d 406, 419 (8th Cir. 2007).

4. Ripeness

The defendants contend that, even if the plaintiffs or some of them have standing, their claims are not ripe for judicial consideration. Because the court found above that the plaintiffs have made sufficient preliminary showing that they have standing, the court turns to consideration of the defendants' challenges to the ripeness of the plaintiffs' claims.

a. Arguments of the parties

The defendants contend that the plaintiffs' claims are not fit for judicial consideration, because they do not raise purely legal issues. Rather, the defendants contend that the plaintiffs seek an advisory opinion from the court on mixed legal and factual issues, such as whether the many different actions purportedly taken by the plaintiffs to obtain raw milk from unidentified sources in numerous states would violate the FDA's regulations. The defendants contend that only in the context of specific enforcement action by the FDA will the agency have gathered the necessary evidence and made the requisite administrative determinations to permit meaningful judicial review. The defendants also argue that the plaintiffs posit a number of *possible* interpretations of the FDA's regulations that they contend *could* render their purported conduct unlawful, but that they do not show that the FDA has ever adopted such interpretations or ever used them as the basis for an enforcement action. The defendants also assert that the plaintiffs do not satisfy the "hardship" prong of the ripeness analysis, because they cannot demonstrate that they have sustained or are immediately in danger of sustaining some direct injury as the result of the challenged regulations. The defendants also argue that they have a strong institutional interest in this court withholding review, because finding that a ripe claim can be based on anyone's construction of FDA regulations, whether such a construction has ever been adopted or applied by the FDA, would waste the FDA's and the court's resources, leaving less resources for actual cases.

The plaintiffs agree that, in order for a declaratory judgment action to be "ripe," the issues should be largely legal in nature, those issues can be resolved without further factual development, and the resolution of the case will largely settle the parties' dispute. The plaintiffs contend that they satisfy these requirements, because they *do* face enforcement action from the FDA. They also argue that, because their allegations must be construed as true, the case presents purely legal issues of whether § 1240.61 and § 131.110 are unconstitutional as applied to them. Moreover, they contend that the issues should be addressed now to resolve this dispute so that the FDA and the plaintiffs can gain clarity on the application, scope, and extent of § 1240.61 and § 131.110.

In reply, the defendants assert that the plaintiffs are unabashedly seeking an advisory opinion, not adjudication of ripe claims, when they acknowledge that their claims are to "gain clarity" on the application, scope, and extent of the regulations.

b. Analysis

As the Eighth Circuit Court of Appeals has explained,

> "The ripeness doctrine flows both from the Article III 'cases' and 'controversies' limitations and also from prudential considerations for refusing to exercise jurisdiction." *Nebraska Pub. Power Dist. v. MidAmerican Energy Co.,* 234 F.3d 1032, 1037 (8th Cir. 2000). The "basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." *Abbott Labs. v. Gardner,* 387 U.S. 136, 148, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967). It is well settled that the ripeness inquiry requires the examination of both "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149, 87 S. Ct. 1507. This court recently determined that "[a] party seeking judicial relief must necessarily satisfy both prongs to at least a minimal degree." *Nebraska Pub. Power,* 234 F.3d at 1039.

Public Water Supply Dist. No. 10 of Cass County, Mo. v. City of Peculiar, Mo., 345 F.3d 570, 572-73 (8th Cir. 2003). The court will consider each of these prongs of the ripeness analysis in turn.

i. Fitness. The Eighth Circuit Court of Appeals has explained that "'[t]he 'fitness for judicial decision' inquiry goes to a court's ability to visit an issue.'" *Public Water Supply Dist. No. 10*, 345 F.3d at 573 (quoting *Nebraska Pub. Power*, 234 F.3d at 1038). More specifically,

> Whether a case is "fit" depends on whether it would benefit from further factual development. *See [Nebraska Pub. Power*, 234 F.3d at 1038]; *see also Nat'l Right to Life Political Action Comm. v. Conner*, 323 F.3d 684, 692-93 (8th Cir. 2003). The case is more likely to be ripe if it poses a purely legal question and is not contingent on future possibilities. *See Nebraska Pub. Power,* 234 F.3d at 1038.

Public Water Supply Dist. No. 10 of Cass County, Mo., 345 F.3d at 573. In contrast, the Eighth Circuit Court of Appeals has held that "to resolve an issue lacking factual development simply to avoid a threatened harm would be to favor expedition over just resolution." *Nebraska Pub. Power Dist. v. MidAmerican Energy Co.*, 234 F.3d 1032, 1039 (8th Cir. 2000); *see also Yankton Sioux Tribe v. Podhrasky*, 606 F.3d 994, 1015 (8th Cir. 2010) (quoting *Nebraska Pub. Power District*). Thus, where "a number of potentially important facts are missing" with respect to the purported application of a regulation or statute, the court may decline to consider the questions presented in the absence of a fully developed record. *Yankton Sioux Tribe*, 606 F.3d at 1015. Similarly, "'[a] claim is not ripe for adjudication if it rests upon "contingent future events that may not occur as anticipated, or indeed may not occur at all."'" *Minnesota Pub. Utils. Comm'n v. FCC*, 483 F.3d 570, 582 (8th Cir. 2007) (quoting *Texas v. United States*, 523 U.S. 296, 300

(1998), in turn quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-581 (1985)).

The court is not persuaded by the defendants' contention that the plaintiffs are seeking an advisory opinion from the court on mixed legal and factual issues, such as whether many different kinds of actions would violate the FDA's regulations. The court also is not persuaded by the defendants' argument that only in the context of specific enforcement action by the FDA will the agency have gathered the necessary evidence and made the requisite administrative determinations to permit meaningful judicial review. Indeed, the court finds that the defendants are challenging the ripeness of the wrong claims: The plaintiffs' claims are not, as the defendants seem to assert, whether the many different actions purportedly taken by the plaintiffs to obtain raw milk from unidentified sources in numerous states *would violate the FDA's regulations*, but *whether the regulations are unconstitutional or otherwise invalid*.

Contrary to the defendants' contentions, this case poses the following essentially legal questions or, at least, questions not contingent on future possibilities, *see Public Water Supply Dist. No. 10 of Cass County, Mo.*, 345 F.3d at 573: (1) whether the regulations in question violate the rights of persons who travel from one state, where it is not legal to purchase raw milk, to another state, where it is legal to purchase raw milk, legally purchase raw milk, then return to the original state where they consume the raw milk themselves or give it to their friends or family members; (2) whether the regulations in question violate the rights of a principal and agent who agree that the agent will obtain raw milk out-of-state, where it is legal to do so, and deliver it to the principal in the principal's home state, where sales of raw milk are not permitted; and (3) whether the regulations in question violate the rights of a producer of raw milk who sells raw milk in an intrastate transaction to persons that he knows are from out of state. The defendants

have failed to identify any potentially important facts that are missing with respect to the purported application of the regulations to these plaintiffs, so that it is not incumbent on the court to decline to exercise jurisdiction over their claims. *Yankton Sioux Tribe*, 606 F.3d at 1015. Although "'[a] claim is not ripe for adjudication if it rests upon "contingent future events that may not occur as anticipated, or indeed may not occur at all,"'" *Minnesota Pub. Utils. Comm'n*, 483 F.3d at 582 (quoting *Texas*, 523 U.S. at 300, in turn quoting *Thomas*, 473 U.S. at 580-581), the court does not believe that principle requires that the plaintiffs be subjected to an actual enforcement action for their claims to be ripe, or no pre-enforcement challenge would ever be ripe. Rather, the court reads that principle to apply to *conduct of the plaintiffs*, and here, there is no contingency concerning whether or what the plaintiffs have done and are continuing to do.

The court concludes that the plaintiffs' claims are "fit" for judicial review.

ii. ***Hardship***. As to the "hardship" prong,

> "[A]bstract injury is not enough. It must be alleged that the plaintiff has sustained or is immediately in danger of sustaining some direct injury as the result of the challenged statute or official conduct." *O'Shea v. Littleton,* 414 U.S. 488, 494, 94 S. Ct. 669, 38 L. Ed. 2d 674 (1974) (internal quotations and citations omitted). "The plaintiffs need not wait until the threatened injury occurs, but the injury must be 'certainly impending.'" *Paraquad, Inc. v. St. Louis Hous. Auth.,* 259 F.3d 956, 958-59 (8th Cir. 2001) (quoting *Babbitt v. United Farm Workers Nat'l Union,* 442 U.S. 289, 298, 99 S. Ct. 2301, 60 L. Ed. 2d 895 (1979)).

Public Water Supply Dist. No. 10 of Cass County, Mo., 345 F.3d at 573.

The plaintiffs contend that denial of review would impose a hardship on them, because they are subject to imminent enforcement of the regulations in question against them. The defendants contend that they have not attempted to enforce the regulations

against any of the plaintiffs, nor have they warned any of the plaintiffs of the possibility of enforcement action by warning letter, so that these plaintiffs cannot show that any injury is certainly impending. The defendants contend that even warning letters would not be enough to give the court subject matter jurisdiction over the plaintiffs' claims, because they do not commit the FDA to enforcement action, citing *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983), and *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1504 (D. Kan. 1992).[9]

The defendants contend that plaintiff Wagoner's allegations of actual enforcement action against him and against one of his principals, Cooper, are "bizarre" and unsupported. The defendants contend that, if the FDA, rather than state officials, had actually ordered the destruction of the raw milk as alleged, the FDA would have done so in a *in rem* seizure action, pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 334, in which Wagoner (and presumably Cooper) would have had the opportunity to appear and object, but there is no evidence of any such action. Interestingly, the defendants do not dispute Wagoner's contention that a FDA agent was present at the destruction of the raw milk, nor do they offer any evidence demonstrating that the destruction of the raw milk was entirely on the authority of Georgia state officials, not the FDA. Under the circumstances, where the court has construed the defendants' challenge to subject matter jurisdiction as essentially facial, the court must take as true the

[9] As noted above, the defendants cited these decisions in support of their contention that courts have "consistently" found that merely receiving a warning letter does not confer standing, because such letters do not commit the FDA to enforcement action. Neither decision stands for the proposition for which the defendants cite them, because the court in each case considered "ripeness," not "standing." *See Biotics Research Corp.*, 710 F.2d at 1376 & 1378; *Clinical Reference Lab., Inc.*, 791 F. Supp. 1503-04. This court will now consider the import of these decisions in the appropriate context of "ripeness."

plaintiffs' allegations that the FDA ordered the destruction of the raw milk that Wagoner was transporting across state lines to distribute to Cooper and others, so that Wagoner and Cooper have, indeed, already been subjected to enforcement action by the FDA pursuant to the regulations in question. Consequently, the court must conclude that the injury that Wagoner and Cooper fear is "certainly impending." *Public Water Supply Dist. No. 10 of Cass County, Mo.,* 345 F.3d at 573 (citations omitted).

As to the "hardship" of the other plaintiffs, the court does not find that the lack of warning letters means that these plaintiffs' claims are not "ripe." The court acknowledges that, in *Biotics Research Corporation* and *Clinical Reference Laboratory*, other courts concluded that warning letters sent to the plaintiffs, warning of possible agency enforcement action, were not enough to make the plaintiffs' claims ripe, because the warning letters did not constitute final agency action that would have established sufficiently imminent injury. *See Biotics Research Corp.*, 710 F.2d at 1376 & 1378; *Clinical Reference Lab., Inc.*, 791 F. Supp. 1503-04. Here, none of the plaintiffs have alleged that they have even received warning letters. The court disagrees with the decisions in *Biotics Research* and *Clinical Reference Laboratory* to the extent that they could be read to require final agency action, or notice from an agency committing the agency to enforcement action, to establish sufficiently imminent injury to show "hardship" and, consequently, "ripeness." Such a rule would mean that no pre-enforcement challenge to agency regulations is *ever* ripe, but the test is whether the plaintiffs have alleged that they have sustained *or are immediately in danger of sustaining* some direct injury as the result of the challenged statute or official conduct. *See Public Water Supply Dist. No. 10 of Cass County, Mo.,* 345 F.3d at 573. The "hardship" prong of the "ripeness" analysis does not require the plaintiff to wait until the threatened injury occurs. *Id.*

For much the same reason that the court found that the direct purchaser plaintiffs had made sufficient preliminary showing of a credible threat of injury, for standing purposes, the court now finds that they have made sufficient preliminary showing that they are in immediate danger of sustaining some direct injury, as the result of the challenged regulations, for ripeness purposes. These plaintiffs have made an essentially unchallenged showing that Wagoner, a similarly-situated plaintiff, was ordered to destroy milk that he had purchased for himself then transported across state lines and that such conduct plausibly falls within the prohibitions of the regulations. Furthermore, for much the same reason that the court found that the producer plaintiff, plaintiff Buck, had made sufficient preliminary showing of a credible threat of injury, for standing purposes, the court now finds that he has made sufficient preliminary showing that he is in immediate danger of sustaining some direct injury, as the result of the challenged regulations, for ripeness purposes. Plaintiff Buck has made an essentially unchallenged showing that a similarly-situated producer was subject to a FDA criminal enforcement action, because, like him, that producer knew that some buyers of his raw milk were from out of state and that they were taking the raw milk back to their own states for human consumption. See Amended Complaint, ¶ 42.

Therefore, the plaintiffs also satisfy the "hardship" prong of the "ripeness" analysis.

c. Summary

That part of the defendants' Motion To Dismiss seeking dismissal of the claims of the plaintiffs on "ripeness" grounds will be denied.

***5. Foreclosure by* Ewing**

The last arrow in the defendants' quiver as they attempt to shoot down the plaintiffs' claims for lack of subject matter jurisdiction is that the plaintiffs' claims for declaratory and injunctive relief barring the government from applying the FDA's regulations are

foreclosed by *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). The plaintiffs dispute the applicability of *Ewing* to their claims.

a. Arguments of the parties

The defendants assert that *Ewing* bars actions for judicial review at preliminary phases of the FDA's administrative procedures, such as whether or not to institute enforcement actions at all. The defendants argue that, *if* the FDA were to determine that the plaintiffs' alleged conduct violates FDA regulations prohibiting the interstate sale and distribution of unpasteurized milk, then the government would have the discretion to initiate a seizure or injunctive action pursuant to provisions of the FDCA, 21 U.S.C. §§ 332 and 334. At that time, the defendants argue, the plaintiffs would have the opportunity to raise and litigate the claims that they advance in the present action. At this time, however, the defendants contend, the plaintiffs' request is for this Court to enjoin all such future enforcement action, but that request is plainly foreclosed by *Ewing* and its progeny.

The plaintiffs contend that *Ewing* is simply not on point, because the Supreme Court has determined that *Ewing* does not apply to a declaratory judgment action, even a pre-enforcement action, in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). Although they acknowledge that *Abbott* has been overturned as to its holding that the Administrative Procedures Act (APA) grants federal courts an independent jurisdictional basis to hear challenges to agency action, they contend that *Abbott* is still controlling on the ability of litigants to bring declaratory judgment actions to challenge the application of final agency action.

In reply, the defendants argue that *Ewing* forecloses the plaintiffs' action, because the plaintiffs expressly prayed for injunctive relief enjoining further enforcement of the regulations against them. In a rather dramatic reformulation of their argument, however,

the defendants also contend that the plaintiffs do not meet the *Abbott* ripeness standard, because the parties here do not agree that the issues presented are purely legal or that the regulations are directed at the plaintiffs in particular, and the FDA has not indicated that immediate compliance with its regulations is expected. Indeed, the FDA argues that it is by no means clear that the regulations in question even touch the plaintiffs' alleged conduct. The defendants contend that this case is more akin to *Toilet Goods Association v. Gardner*, 387 U.S. 158 (1967), in which the Supreme Court held that the judicial review was not appropriate where the court had no idea whether or when the challenged FDA regulation would be enforced or what reasons the Commissioner would give to justify the enforcement order. The defendants contend that the Court reached that conclusion in *Toilet Goods*, even though there was no question that the FDA's regulation constituted final agency action and the challenge to it was a purely legal question. The defendants argue that, just as in *Toilet Goods*, the present dispute requires additional factual development—whether through plaintiffs' submission of a citizen petition or a FDA investigation and enforcement action—before this court could have sufficient information to determine whether the challenged regulations even apply to the plaintiffs' conduct.

b. Analysis

The court finds the defendants' reliance on *Ewing* to be particularly ill-founded. This is so, even though the defendants are correct that the plaintiffs pray, *inter alia*, for "[a]n injunction enjoining any further enforcement, civil, criminal, administrative or otherwise, of [the regulations] against Plaintiffs." Amended Complaint at 26, ¶ G. Although *Ewing* bars judicial review of and injunctive relief against preliminary phases of administrative procedures to enforce regulations, including the determination of whether or not to institute an enforcement action, *see Ewing*, 339 U.S. at 600-01, nothing in *Ewing* bars a court from hearing an action for declaratory judgment concerning the validity of

final agency regulations in which there is an incidental, perhaps overbroad, prayer for injunctive relief pursuant to the declarations sought. The bar in *Ewing* on enjoining preliminary phases of administrative procedures to enforce regulations simply has no application, where there are no administrative procedures to enforce the regulations at issue currently afoot. The defendants' reading of *Ewing* would preclude any and all pre-enforcement declaratory challenges to regulations if there is a prayer for incidental injunctive relief. *Ewing* does not reach so far.

Moreover, contrary to the defendants' belated retrenchment, this case is closer to *Abbott* than to *Toilet Goods*. Contrary to the defendants' contentions, the court concluded above that the challenge by the plaintiffs poses the following legal questions, or at least questions not contingent on future possibilities: (1) whether the regulations in question violate the rights of persons who travel from one state, where it is not legal to purchase raw milk, to another state, where it is legal to purchase raw milk, legally purchase raw milk, then return to the original state where they consume the raw milk themselves or give it to their friends or family members; (2) whether the regulations in question violate the rights of a principal and agent who agree that the agent will obtain raw milk out-of-state, where it is legal to do so, and to deliver it to the principal in the principal's home state, where sales of raw milk are not permitted; and (3) whether the regulations in question violate the rights of a producer of raw milk who sells raw milk in an intrastate transaction to persons that he knows are from out of state. The defendants have failed to identify any potentially important facts that must be determined through a citizen petition or agency enforcement action that are necessary to determine the applicability of the regulations to the conduct of these plaintiffs, where the court held, above, that the plaintiffs have made an adequate preliminary showing that the regulations plausibly proscribe their conduct and that the FDA stands ready to enforce the regulations against conduct such as theirs.

Thus, the questions presented here are purely legal and based on undisputed factual circumstances, and it appears that the FDA does stand ready to enforce compliance with the regulations, to the extent that the FDA has purportedly already enforced them against these plaintiffs and allegedly similarly situated persons. *Compare Abbott*, 387 U.S. 146-47 (finding that an action for judicial review was not foreclosed by *Ewing* where the FDA had already formally promulgated the regulation in question, the regulation was "self-operative," and foreclosure of an action in such circumstances would immunize nearly all agency rule-making from review under the APA, and while *Ewing* barred interference with the early stages of administrative determinations as to specific facts, it did not bar well-established jurisdiction of the federal courts to hear suits under the Declaratory Judgment Act), *with Toilet Goods*, 387 U.S. at 163 (the Court found no jurisdiction where it had "no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order").

The defendants' final attack on the court's subject matter jurisdiction over the plaintiffs' claims, thus, fails, at least on the present record.

6. Summary

The court concludes—in light of the present submissions and the failure of the defendants to mount an unambiguously factual challenge to subject matter jurisdiction—that the plaintiffs have standing to pursue their claims and that those claims are ripe for judicial determination. The court reiterates, however, that these conclusions are preliminary, and turn in large part on the court's obligation to take as true the plaintiffs' jurisdictional allegations, in the absence of a full-fledged factual challenge to subject matter jurisdiction and a request for an evidentiary hearing by the defendants.

B. Failure To Exhaust Administrative Remedies

The defendants also mount several challenges pursuant to Rule 12(b)(6) to the plaintiffs' Amended Complaint on the ground that the Amended Complaint fails to state claims upon which relief can be granted. However, the court finds that only one of those challenges, the plaintiffs' alleged failure to exhaust administrative remedies, must be addressed at this time, in light of the court's strictly preliminary determination that the plaintiffs have standing and that their claims are ripe. Although failure to exhaust administrative remedies is not a jurisdictional impediment, *see Teva Pharm. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42, 51 (D.D.C. 2009), *rev'd on other grounds*, 595 F.3d 1303 (D.C. Cir. 2010), the defendants' failure-to-exhaust challenge is, nevertheless, another version of the defendants' overarching contention that the plaintiffs' claims are not yet ready for judicial determination.

1. Arguments of the parties

The defendants contend that dismissal is appropriate, where the plaintiffs have failed to avail themselves of the administrative process. They contend that the plaintiffs have made no attempt to avail themselves of, much less exhaust, administrative remedies available to them, consisting of a citizen's petition with the FDA pursuant to 21 C.F.R. §§ 10.25 and 10.30. The defendants contend that, pursuant to 21 C.F.R. § 10.45(b), before any legal action is filed in a court, a party must first file a citizen petition to request that the Commissioner take or refrain from taking any form of administrative action and, pursuant to 21 C.F.R. § 10.45(d), the FDA's response to such a petition constitutes reviewable final agency action. Here, the defendants argue that the plaintiffs' attempt to bypass the administrative process means that they have precluded meaningful and efficient judicial review, which would have allowed the FDA to consider and address the plaintiffs' concerns and which could have resolved or at least crystalized the issues.

The plaintiffs counter that exhaustion of administrative remedies does not apply to a declaratory judgment action such as this. The plaintiffs contend that there are no administrative remedies for them to exhaust, because the requirement for administrative proceedings, on its face, does not apply to an as-applied challenge to the constitutionality of the regulations through a declaratory judgment action. The plaintiffs also contend that promulgation of the regulations is reviewable final agency action. The plaintiffs next contend that the FDA lacks authority to rule on the constitutionality of the regulations in question, citing *Mathews v. Diaz*, 426 U.S. 67, 76 (1976). They also argue that the FDA has already exhibited its bias or predetermination of the issues, because it will not modify, amend, or revoke the regulations in question, where it has already been presented with a citizen's petition (by persons not parties here) asking the agency to amend or rescind the regulations in question, but the agency has taken no action upon that citizen's petition within the required time frame. Finally, assuming that an administrative remedy exists, the plaintiffs argue that pursuing that remedy would be an exercise in futility, because the FDA has made clear in public statements that it believes that raw milk should not be consumed by anyone and has refused to debate the issue in available public fora.

2. Analysis

a. The administrative exhaustion requirement

Rule 12(b)(6) provides for a motion to dismiss for failure to state a claim upon which relief can be granted. The defendants assert that failure to exhaust administrative remedies under FDA regulations warrants dismissal pursuant to Rule 12(b)(6), citing *Association of Am. Physicians & Surgs., Inc. v. FDA*, 539 F. Supp. 2d 4, 22 (D.D.C. 2008). This court will assume, without deciding, that failure to exhaust the FDA's administrative remedies warrants dismissal for failure to state a claim pursuant to Rule 12(b)(6), where exhaustion of administrative remedies is required by statute or regulation.

As the defendants point out, "[t]he basic purpose of the exhaustion doctrine is to allow an administrative agency to perform functions within its special competence—to make a factual record, to apply its expertise, and to correct its own errors so as to moot judicial controversies." *See Parisi v. Davidson*, 405 U.S. 34, 37 (1972). If interested parties were allowed to bypass administrative remedies, the entire regulatory process would be undermined, and "[c]ourts would constantly have to address new arguments that were never presented to the agency." *Association of Am. Physicians & Surgeons, Inc.*, 539 F. Supp. 2d at 22. Moreover, "[a]n administrative agency, which is not subject to Article III of the Constitution of the United States and related prudential limitations, may issue a declaratory order in mere anticipation of a controversy or simply to resolve an uncertainty." *Pfizer, Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999) (citing *Metropolitan Council of NAACP Branches v. FCC*, 46 F.3d 1154, 1161 (D.C. Cir. 1995)).

However, as the plaintiffs point out, a party "cannot 'properly be required to exhaust a remedy which may not exist.'" *Parisi*, 405 U.S. at 44 (quoting *Noyd v. Bond*, 395 U.S. 683, 698 n.11 (1969)). Moreover,

> Courts have the discretion to decline to require exhaustion where a plaintiff would be irreparably harmed by delay, where the agency lacks the power to grant effective relief, or where exhaustion would be futile. *McCarthy v. Madigan*, 503 U.S. 140, 146-49, 112 S.Ct. 1081, 117 L.Ed.2d 291 (1992). Exhaustion is futile when there is a certainty of an adverse decision, *Randolph-Sheppard Vendors v. Weinberger*, 795 F.2d 90, 105 (D.C. Cir. 1986), or when the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider." *James v. HHS*, 824 F.2d 1132, 1137 (D.C. Cir. 1987).

Teva Pharm., 638 F. Supp. 2d at 51; *see also Chorosevic v. MetLife Choices*, 600 F.3d 934, 945 (8th Cir. 2010) (also recognizing, in the ERISA context, that exhaustion of

administrative remedies may be excused if they would be futile, but observing, "'Unsupported and speculative claims of futility do not excuse a claimant's failure to exhaust his or her administrative remedies,'" quoting *Midgett v. Washington Group Int'l Long Term Disability Plan*, 561 F.3d 887, 898 (8th Cir. 2009)). Matters outside the agency's power to grant effective relief include determination of the constitutionality of a statute, *see McCarthy*, 503 U.S. at 147-48, and, presumably, the constitutionality of a regulation.

b. The necessity of exhaustion of the present claims

These principles bring the court to the question of whether and for what questions administrative exhaustion is required by FDA regulations. As a colleague in a sister district has concisely explained, "FDA regulations require that, before filing suit in court, a party requesting that the FDA take or refrain from taking an action must first use the citizen petition process set forth in 21 C.F.R. § 10.25." *Teva Pharm*, 638 F. Supp. 2d at 51 (citing 21 C.F.R. § 10.45(b)). The FDA's response to a citizen petition is deemed to be a "'final agency action . . . reviewable in the courts.'" *Pfizer*, 182 F.3d at 979-80 (quoting 21 C.F.R. § 10.45(d)); *Schering Corp. v. FDA*, 51 F.3d 390, 393 (3d Cir. 1995).

Somewhat more specifically, 21 C.F.R. § 10.25(a) provides that "[a]n interested person may petition the Commissioner [1] *to issue, amend, or revoke a regulation or order*, or [2] *to take or refrain from taking any other form of administrative action*." (Emphasis added). That regulation provides, further, that "a petition must be either . . . [i]n the form specified [for specific agency actions], or . . . in the form of a citizen petition in § 10.30." 21 C.F.R. § 10.25(a). Section 10.45(b) makes certain administrative exhaustion mandatory:

> (b) A request that the Commissioner *take or refrain from taking any form of administrative action* must first be the

> subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act. *If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a)* or, where applicable, a hearing under § 16.1(b), *the Commissioner shall request dismissal of the court action* or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

21 C.F.R. § 10.45(b) (emphasis added). Although this exhaustion requirement expressly applies to requests that the Commissioner "take or refrain from taking any form of administrative action," one category of requests that may be asserted in an administrative petition pursuant to § 10.25(a), conspicuous by its absence is any reference to the other category of requests identified in § 10.25(a), requests that the Commissioner "issue, amend, or revoke a regulation or order." *See* 21 C.F.R. § 10.25(b).

Even so, this court is not convinced that the plaintiffs' claims fall into *either* of the categories of claims for which a citizen petition is appropriate or required pursuant to 21 C.F.R. § 10.25(b). If this action were for review of a specific administrative enforcement action, then it clearly would fall within the scope of the FDA's administrative remedies, as an action requesting that the Commissioner "refrain from taking [a] form of administrative action," and exhaustion of administrative remedies would clearly be required. 21 C.F.R. §§ 10.25(a) & 10.45(b). It is not. It is, instead, a challenge to the validity and constitutionality of certain FDA regulations, and only incidentally seeks declaratory and injunctive relief against enforcement of the regulations against the plaintiffs *on the basis of the unconstitutionality of the regulations*. Moreover, a determination of the

constitutionality of the regulations falls outside the scope of agency expertise. *Cf. McCarthy*, 503 U.S. at 147-48 (matters outside the agency's power to grant effective relief include determination of the constitutionality of a statute). Even though the plaintiffs' challenge to the regulations is purportedly an "as applied" challenge, the FDA has not shown that it is necessary to make a factual record, apply its expertise, or correct its own errors in order to resolve the claims presented, *see Parisi*, 405 U.S. 37 (identifying areas of special competence of administrative agencies), where the question ultimately presented by the plaintiffs' claims is whether the regulations are constitutional. In short, this is a case in which an administrative remedy does not exist and, therefore, exhaustion of such a non-existent remedy cannot be required. *Id.*

The part of the defendants' Motion To Dismiss seeking dismissal of the plaintiffs' claims for failure to exhaust administrative remedies will be denied.

c. The prudence of exhaustion of questions ante

On the other hand, there *are* questions ante to the plaintiffs' constitutional claims that would fall within the scope of a citizen petition pursuant to § 10.25, if presented as a request that the FDA take administrative action to interpret the authorizing statutes and regulations. Such a request for agency action also falls squarely within the administrative agency's expertise.

More specifically, one of the fundamental disputes in this is that the plaintiffs assume, albeit supported by some circumstantial evidence, that the FDA believes that the plaintiffs' conduct falls within the proscriptions of § 1240.61, while the defendants' assert that the FDA has not and does not intend to enforce the regulations against any of the plaintiffs or persons similarly situated to the plaintiffs. In the context of this dispute, the precise question appropriate for administrative determination, in the first instance, is whether § 1240.61 applies to and proscribes the conduct of (1) persons who travel from

one state, where it is not legal to purchase raw milk, to another state, where it is legal to purchase raw milk, legally purchase raw milk, then return to the original state where they consume the raw milk themselves or give it to their friends or family members; or (2) a principal and agent who agree that the agent will obtain raw milk out-of-state, where it is legal to do so, and to deliver it to the principal in the principal's home state, where sales of raw milk are not permitted; or (3) a producer of raw milk who sells raw milk in an intrastate transaction to persons that he knows are from out of state. This question presents constituent questions of the scope of the authorizing statutes and the regulations at issue, including whether the plaintiffs' conduct involves or affects "interstate commerce" sufficiently to fall within the proscriptions of § 1240.61, and, still more specifically, whether the plaintiffs' conduct constitutes "delivery [of raw dairy products] into interstate commerce" or "distribution" of raw dairy products after shipment in interstate commerce.

As noted above, even in the absence of a "live" controversy, "[a]n administrative agency, which is not subject to Article III of the Constitution of the United States and related prudential limitations, may issue a declaratory order in mere anticipation of a controversy or simply to resolve an uncertainty." *Pfizer,* 182 F.3d at 980. An administrative determination on these questions might, in turn, resolve finally the questions about the plaintiffs' standing and the ripeness of their claims, which the court has not finally resolved here, in the absence of a clear factual challenge. *See Parisi*, 405 U.S. at 37 (administrative exhaustion may, through the application of agency expertise, moot judicial controversies).

The court is not convinced by the plaintiffs' assertions that any administrative proceedings would be futile. *See, e.g., Teva Pharm.*, 638 F. Supp. 2d at 51 (a claimant need not exhaust futile administrative remedies). The allegedly entrenched position attributed to the FDA by the plaintiffs—that raw milk should not be consumed by

anyone—simply does not directly implicate any of the questions posed just above. Nor does the FDA's alleged inaction on a citizen petition by a non-party, asking the FDA to amend or rescind § 1240.61 and/or § 131.110 to allow the interstate shipment of raw dairy products between two different states in the United States that both allow the legal sale of raw dairy products, *see* Plaintiffs' Resistance, Exhibit D, demonstrate that a citizen petition posing different questions—the questions ante identified above—is necessarily futile. Indeed, the court finds the plaintiffs' contentions that administrative proceedings *on any question* would be futile to be, at best, speculative and, hence, insufficient to excuse exhaustion of the questions ante identified just above. *Chorosevic*, 600 F.3d at 945 ("'Unsupported and speculative claims of futility do not excuse a claimant's failure to exhaust his or her administrative remedies,'" quoting *Midgett*, 561 F.3d at 898).

Consequently, the court finds that the prudent course is to stay proceedings to allow the plaintiffs to determine whether or not to pursue a citizen petition presenting to the agency the questions ante posed above, then revisit, if necessary, the questions of standing, ripeness, and failure to state claims upon which relief can be granted.

III. CONCLUSION

Faced with the uncertain nature of the defendants' challenge to the court's subject matter jurisdiction, the court has construed the challenge as essentially a preliminary, facial one. The court finds, however, that the plaintiffs have made sufficient preliminary showing of standing and ripeness to deny the defendants' Motion To Dismiss for lack of subject matter jurisdiction, without prejudice to reassertion of a full factual challenge. Although the court does not find that administrative exhaustion is required for the plaintiffs' present claims, the court does find that it would be prudent to allow the plaintiffs

time to pursue a citizen petition pursuant to 21 C.F.R. § 10.25 raising certain questions ante, identified above.

THEREFORE,

1. That part of the defendants' April 26, 2010, Motion To Dismiss (docket no. 10) asserting lack of subject matter jurisdiction is **denied**, but without prejudice to a full factual challenge to subject matter jurisdiction after expiration of the stay imposed below;

2. That part of the defendants' April 26, 2010, Motion To Dismiss (docket no. 10) asserting failure to state a claim upon which relief can be granted is **denied** as to failure to exhaust administrative remedies, but **ruling is reserved** on the remainder of the defendants' Motion To Dismiss asserting failure to state claims upon which relief can be granted;

3. Proceedings in this court are **stayed for sixty days** from the date of this order to allow the plaintiffs the opportunity to decide whether or not to pursue a citizen petition pursuant to 21 C.F.R. § 10.25 asking the Commissioner to take administrative action in the form of interpretation of the authorizing statutes and regulations in light of the questions ante posed herein.

   a. If the plaintiffs choose to pursue a citizen petition, the court will continue the stay until the completion of the administrative proceedings on that petition or until the agency has failed to take timely action on the citizen petition.

   b. If the plaintiffs decline to pursue a citizen petition raising the questions posed just above, the court will entertain a renewed, and clearly factual challenge to subject matter jurisdiction, and will address the remainder of the defendants' Motion To Dismiss for failure to state claims upon which relief can be granted.

c. The parties shall file, separately or jointly, a **status report** at least every thirty days from the date of this order advising the court as to the necessity of continuing or lifting the stay.

4. The plaintiffs' July 24, 2010, Motion To Admit Newly Discovered Evidence (docket no. 24) is **granted**, and the court has considered the purportedly newly discovered evidence in question for whatever probative value the court found that such evidence had.

IT IS SO ORDERED.

DATED this 18th day of August, 2010.

Mark W. Bennett

MARK W. BENNETT
U. S. DISTRICT COURT JUDGE
NORTHERN DISTRICT OF IOWA