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

FARM-TO-CONSUMER LEGAL DEFENSE FUND, et al.,	)	
Plaintiffs,	)	
v.	)	No. C 10-4018-MWB
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

BRIEF IN SUPPORT OF UNITED STATES' MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

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I. INTRODUCTION

The United States, on behalf of the United States Department of Health and Human Services ("HHS"), Kathleen Sebelius, in her official capacity as Secretary of HHS, and Margaret Hamburg, Commissioner of Food and Drugs, United States Food and Drug Administration ("FDA") (collectively, "Defendants") submits this brief in support of its Motion to Dismiss Plaintiffs' Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

Plaintiffs challenge regulations promulgated by FDA under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a ("FDCA"), and the Public Health Service Act ("PHSA"), 42 U.S.C. §§ 201-300ii, that prohibit the sale or distribution in interstate commerce of unpasteurized milk and milk products ("unpasteurized milk") for human consumption. Plaintiffs contend that the challenged regulations violate the Administrative Procedure Act ("APA"), run afoul of the non-delegation doctrine, infringe upon their constitutional right to travel, and violate their substantive due process rights. Plaintiffs seek declaratory and injunctive relief barring the government from applying FDA's regulations to them.[1]

[1] Plaintiffs also claim that "[a] preliminary injunction is necessary," Am. Compl. ¶ 3, but they have not filed "a separate motion requesting such relief" as required by Local Rules 65 and 7(j). Because Plaintiffs have not complied with the Local Rules,

Plaintiffs are individuals who purchase unpasteurized milk in states where those purchases are lawful and then transport the products for personal consumption into states where the sale of such products is unlawful, Am. Compl. ¶¶ 6-29, who contract with an agent to obtain unpasteurized milk from a state where such products are lawful and then receive them in a state where the sale of such products is unlawful, *id.* ¶¶ 30-35, who sell unpasteurized milk to out-of-state residents in a state where those sales are lawful, *id.* ¶¶ 36-43, and a non-profit organization that "defends and protects the right of farmers to directly provide, and for consumers to directly obtain, unprocessed and processed farm foods" and whose members "are strongly opposed to the enforcement" of FDA's regulations, *id.* ¶¶ 4-5, 51-54. Plaintiffs seek a ruling by this Court that FDA's regulations are illegal as applied to them so that they may "travel across State lines with legally obtained raw dairy products; . . . provide for the care and well being of themselves and their families;" and "produce, obtain and consume the foods of their choice." *Id.* ¶ 60.

Noticeably absent from plaintiffs' Amended Complaint, however, is any allegation that FDA's regulations have ever been interpreted or enforced in the manner feared by plaintiffs. In fact, the government has neither brought nor threatened to bring a single enforcement action against consumers who purchase unpasteurized milk for personal consumption or retailers of such products who do not engage in interstate commerce. Plaintiffs have no standing to bring this speculative pre-enforcement challenge, their case is not ripe, and long standing Supreme Court precedent establishes that FDA enforcement actions may not be enjoined. Moreover, plaintiffs failed to exhaust their

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their request for preliminary injunctive relief should be denied.

administrative remedies prior to bringing suit and their claims are insufficient as a matter of law because the challenged regulations do not represent an impermissible delegation of legislative authority, were not promulgated in excess of FDA's statutory authority, and do not infringe upon the constitutional right to travel. Finally, plaintiffs' assertion of a new "fundamental right" to produce, obtain, and consume unpasteurized milk lacks any support in law. Plaintiffs' Amended Complaint should therefore be dismissed.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(1) mandates the dismissal of a case where the court lacks subject matter jurisdiction. The party invoking judicial review bears the "burden of establishing that a cause of action lies within the limited jurisdiction of the federal courts." *Ark. Blue Cross & Blue Shield v. Little Rock Cardiology Clinic, P.A.*, 551 F.3d 812, 816 (8th Cir. 2009). Where a defendant brings a "motion to dismiss for lack of jurisdiction under Rule 12(b)(1) [that] is limited to a facial attack on the pleadings," the action "is subject to the same standard as a motion brought under Rule 12(b)(6)." *Mattes v. ABC Plastics, Inc.*, 323 F.3d 695, 698 (8th Cir. 2003); *see also Titus v. Sullivan*, 4 F.3d 590, 593 (8th Cir. 1993).

A complaint should be dismissed under Rule 12(b)(6) for failure to state a claim if it appears beyond a doubt that the plaintiff can prove no set of facts in support of the claim that would entitle the plaintiff to relief. *See Craig Outdoor Adver., Inc. v. Viacom Outdoor, Inc.*, 528 F.3d 1001, 1023 (8th Cir. 2008). Although "'a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels

and conclusions.'" *Benton v. Merrill Lynch & Co., Inc.*, 524 F.3d 866, 870 (8th Cir. 2008) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Moreover, "in treating the factual allegations of a complaint . . . as true pursuant to Rule 12(b)(6), the court must 'reject conclusory allegations of law and unwarranted inferences.'" *McLeodUSA Telcomms. Servs. v. Qwest Corp.*, 469 F. Supp. 2d 677, 688 (N.D. Iowa 2007) (quoting *Silver v. H&R Block*, 105 F.3d 394, 397 (8th Cir. 1997)).

III. STATUTORY AND REGULATORY BACKGROUND

A. The PHSA and the Interstate Ban on Unpasteurized Milk, 21 C.F.R. § 1240.61

FDA is authorized under the PHSA, 42 U.S.C. § 264(a), to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one state to another.[2] Congress used broad statutory language in the PHSA and placed no limitation on the kinds or sources of communicable diseases that FDA could address through regulations issued under 42 U.S.C. § 264(a). *See Louisiana v. Matthews*, 427 F. Supp. 174 (E.D. La. 1977) ("Congress has granted broad, flexible powers to federal health authorities who must use their judgment in attempting to protect the public against the spread of communicable disease."); *see also* 21 C.F.R. § 1240.3(b) (defining "communicable diseases" expansively). As "remedial legislation" aimed at protecting the public health, the PHSA "is entitled to

[2] The statute grants this authority to the Surgeon General with the approval of the Secretary. The Office of Surgeon General was abolished on June 25, 1966, and all of its functions were transferred to the Secretary of Health, Education, and Welfare, now the Secretary of HHS, by the 1966 Reorganization Plan No. 3, 42 U.S.C. § 202. The authority of the HHS Secretary has been delegated to FDA. *See* FDA Staff Manual Guide, vol. II, § 1410.10 (listing delegations of authority), *available at* http://www.fda.gov/AboutFDA/ReportsManualsForms/ StaffManualGuides/default.htm.

liberal construction." *Indep. Turtle Farmers of La. v. United States*, No. 07-856, 2010 WL 1286392, at *12 n.19 (W.D. La. Mar. 30, 2010).

Pursuant to its authority under of the PHSA, and in furtherance of its mandate to prevent the introduction, transmission, or spread of communicable diseases from one state to another, FDA promulgated a ban on the interstate sale of unpasteurized milk:

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

21 C.F.R. § 1240.61(a);[3] *see also* 52 Fed. Reg. 29,509 (Aug. 10, 1987); *Public Citizen v. Heckler*, 602 F. Supp. 611, 613 (D.D.C. 1985) ("*Public Citizen I*") (finding that "the [PHSA]'s authorization for regulations to control communicable diseases" provided "ample legal authority" for FDA to institute the ban). Distributing unpasteurized milk in interstate commerce in violation of 21 C.F.R. § 1240.61 is a crime under the PHSA, 42 U.S.C. § 271(a). Because the ban on unpasteurized milk is applicable only to interstate commerce, however, individual states presently control whether unpasteurized milk is available to their residents through intrastate sales. *But see Public Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D.D.C. 1986) ("*Public Citizen II*") (observing that "it is within HHS's authority . . . to institute an intrastate ban as well").

FDA promulgated 21 C.F.R. § 1240.61 in 1987, after spending thirteen years collecting and evaluating scientific information regarding the health risks of unpasteurized milk, holding a public hearing that resulted in over 300 comments, and

[3] "Milk products" are defined in 21 C.F.R. § 1240.3(j) as "[f]ood products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals."

ultimately concluding that consumption of these products was linked to the outbreak of serious disease. *See Public Citizen II*, 653 F. Supp. at 1232-33 n.3 (describing the "compelling evidence" before FDA in the rulemaking, including a "link between raw milk" and "outbreaks of two serious bacterial diseases, campylobacteriosis and salmonellosis, which on rare occasions result in death"); *see also* 52 Fed. Reg. at 29,510-512. In fact, FDA was *ordered* by the court in *Public Citizen II* to promulgate a regulation banning interstate distribution of unpasteurized milk in light of "overwhelming evidence of the risks associated with the consumption of raw milk." 653 F. Supp. at 1238; *see also id.* at 1241 ("It is undisputed that all types of raw milk are unsafe for human consumption and pose a significant health risk . . . . There is no longer any question of fact as to whether the consumption of raw milk is unsafe.").

B. The FDCA and the Milk Standard of Identity, 21 C.F.R. § 131.110

In enacting the FDCA, Congress directed FDA to "protect the public health by ensuring that—foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2). The Supreme Court has repeatedly recognized that "one of the Act's core objectives is to ensure that any product regulated by the FDA is safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120, 133 (2000); *see also United States v. Park*, 421 U.S. 658, 671 (1975) ("[T]he public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care . . . .") (citation and quotation marks omitted). As the Eighth Circuit Court of Appeals has recognized, "[t]he [FDCA] is a remedial statute designed for the protection of the consumer." *United States v. Naremco, Inc.*, 553 F.2d 1138, 1141 (8th Cir. 1977).

Among the FDCA's many provisions aimed at safeguarding the food supply is 21 U.S.C. § 341, which directs FDA to "promulgate regulations fixing and establishing for any food, under its common or usual name . . . , a reasonable definition and standard of identity . . . [or] quality" where "in the judgment of the [Commissioner] such action will promote honesty and fair dealing in the interest of consumers."[4] *See also Fed. Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 232 (1943) ("[T]he legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, sold under a common or usual name, so as to give to consumers who purchase it under that name assurance that they will get what they may reasonably expect to receive.").

Pursuant to this authority, and in furtherance of its public health mission, FDA promulgated a standard of identity for milk in 1973, defining it as "the lacteal secretion . . . obtained by the complete milking of one or more healthy cows" that "in final package form for beverage use shall have been pasteurized or ultrapasteurized." 21 C.F.R. § 131.110(a); *see also* 38 Fed. Reg. 27,924 (Oct. 10, 1973) (finding that "pasteurization assures the destruction of pathogenic bacteria that may be present"). The milk standard of identity is "designed to inform consumers about the content of the milk they purchase and to protect against fraud and misrepresentation." *Shamrock Farms Co. v. Veneman*, 146 F.3d 1177, 1178 (9th Cir. 1998).

Any product labeled "milk" in interstate commerce "in final package form for beverage use" that does not conform to the standard of identity for milk is misbranded

[4] Although the FDCA refers to the authority of the Secretary of HHS, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2); *see also* FDA Staff Manual Guide, vol. II, § 1410.10.

under the FDCA. *See* 21 U.S.C. § 343(g). The introduction of a misbranded food into interstate commerce is a violation of the FDCA, 21 U.S.C. § 331(a), that may result in civil and criminal liability. *See* 21 U.S.C. §§ 332-334. Because the standard of identity regulations apply only to foods in interstate commerce, the requirement of 21 C.F.R. § 131.110 that milk be pasteurized "does not conflict with the right of individual states to authorize the *intra*state distribution of raw milk to consumers." 38 Fed. Reg. 27,924 (emphasis added); *see also* 21 U.S.C. § 343-1(a)(1) ("[N]o State . . . may directly or indirectly establish . . . as to any food *in interstate commerce*—any requirement for a food which is the subject of a standard of identity . . . that is not identical to such standard of identity.") (emphasis added). The intrastate sale of unpasteurized milk is presently legal, subject to various restrictions, in twenty-eight states. Am. Compl. ¶ 94; *see also* Laura Landro, *A Clash Over Unpasteurized Milk Gets Raw*, Wall St. J., Mar. 30, 2010.

IV. ARGUMENT

Plaintiffs contend that FDA's regulations prohibiting the sale and distribution of unpasteurized milk in interstate commerce violate the APA because the regulations exceed FDA's statutory authority and are arbitrary and capricious, constitute an illegal delegation of power in violation of the non-delegation doctrine, infringe upon the constitutional right to travel, and violate plaintiffs' substantive due process rights. As set forth below, this Court lacks subject matter jurisdiction over these contentions, and, even if this were not so, plaintiffs have failed to state a claim. Defendants' motion to dismiss should therefore be granted.

A. This Court Lacks Subject Matter Jurisdiction Over Plaintiffs' Claims.

Plaintiffs do not satisfy the "case or controversy" requirement of Article III because they do not have standing, and their claims are not ripe for judicial review. In addition, under settled Supreme Court precedent, courts lack jurisdiction to enjoin FDA from enforcing the FDCA. Plaintiffs' Amended Complaint should therefore be dismissed under Rule 12(b)(1).

1. Plaintiffs Lack Standing.

This Court "must first address whether plaintiffs have alleged a case or controversy within the meaning of Article III of the Constitution or whether they assert only abstract questions not currently justiciable by a federal court." *Zanders v. Swanson*, 573 F.3d 591, 593 (8th Cir. 2009). Whether plaintiffs have standing is "perhaps the most important" test of justiciability. *Allen v. Wright*, 468 U.S. 737, 750 (1984). To establish standing, plaintiffs must demonstrate "(1) injury in fact, (2) a causal connection between that injury and the challenged conduct, and (3) the likelihood that a favorable decision by the court will redress the alleged injury." *Young Am. Corp. v. Affiliated Computer Servs.*, 424 F.3d 840, 843 (8th Cir. 2005) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

Plaintiffs cannot make the requisite showing of injury in fact. They claim that they are presently suffering an injury because FDA's regulations deprive them of their constitutional rights, but as explained in Section IV.C below, plaintiffs' constitutional claims fail as a matter of law. Am. Compl. ¶ 57. Plaintiffs also contend that the "threat of an enforcement action by FDA" is a future injury sufficient to confer standing upon them. *Id.* ¶ 58. But to constitute an injury for standing purposes, plaintiffs must show

that there is a "real and immediate threat" that FDA will institute an enforcement action against them. *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974); *see also Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (requiring a plaintiff to show that "the injury is certainly impending") (citation and quotation marks omitted).

Plaintiffs have not made such a showing. They do not point to a single enforcement action the government has brought against others similarly situated (*i.e.*, individuals buying unpasteurized milk for personal consumption or retailers of unpasteurized milk purportedly not engaging in interstate commerce), nor do they allege that FDA has in any way signaled an intention to enforce the challenged regulations against plaintiffs. For example, although FDA ordinarily gives "individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action" by issuing a Warning Letter to potential targets of enforcement actions, plaintiffs do not allege that they have received such a letter. FDA, *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (Mar. 2009) ("Warning Letters are issued to achieve voluntary compliance and to establish prior notice."), *available at* http://www.fda.gov/ICECI/Compliance Manuals/RegulatoryProceduresManual/default.htm. And even if they had, courts have consistently found that receiving a Warning Letter does not confer standing because "such letters do not commit the FDA to enforcement action." *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983); *see, e.g., Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1504 (D. Kan. 1992) ("Such letters do not bind the agency to the views expressed in them.").

Rather than point to a concrete future injury, plaintiffs insist that their abstract fear of an enforcement action leaves them "faced with a Hobson's choice." Am. Compl.

¶ 59. The United States District Court for the District of Colorado in *Regenerative Sciences, Inc. v. FDA*, recently considered this very argument from a plaintiff who had *already* received a Warning Letter from FDA. No. 09-411, 2010 WL 1258010, at *7 (D. Colo. Mar. 26, 2010) (weighing the plaintiff's claim that FDA's regulations forced it "to make the Hobson's choice between obeying the order or incur the risks of noncompliance, such as the possibility of warning letter, seizure, injunction, [or] criminal prosecution") (quotation marks omitted). The court dismissed the case for lack of jurisdiction after finding that:

> the perceived threat of enforcement action is felt no more strongly by [the plaintiff] than by any other entity anticipating a disagreement with FDA over whether or how its activities should be regulated. The fact remains that [the plaintiff] has not shown any specific concrete action taken by the FDA that has harmed it or any specific losses it has suffered as a result of FDA action. Therefore, the Court concludes that [the plaintiff's] risk of future FDA enforcement actions is too speculative to warrant judicial intervention . . . .

Id. at *8. So too here. Plaintiffs have failed to establish a threatened future injury sufficient for standing. *See Nat'l Fed'n of the Blind v. Cross*, 184 F.3d 973, 981 (8th Cir. 1999) ("Without a concrete present or future injury, the [plaintiffs] would not have standing to sue"); *see also Zanders*, 573 F.3d at 594 (ruling that, even in the First Amendment context, a plaintiff "must face a credible threat of present or future prosecution under the statute . . . to confer standing to challenge [its] constitutionality").

Finally, plaintiffs are also without standing because there is no causal connection between their alleged injury and FDA's regulations, and a favorable ruling from this Court would not remedy their alleged injury. *See Hodak v. City of St. Peters*, 535 F.3d 899, 903 (8th Cir. 2008). As plaintiffs repeatedly acknowledge in their Amended Complaint, unpasteurized milk is unavailable in many states, including Iowa, because

state laws prohibit its sale. *See, e.g.,* Am. Compl. ¶¶ 7, 94. A ruling that FDA's interstate commerce regulations may not be applied to plaintiffs would not make such sales lawful in Iowa or many other states. *See Advantage Media, L.L.C. v. City of Eden Prairie*, 456 F.3d 793, 801 (8th Cir. 2006) (finding redressability was lacking where the desired course of conduct "would still violate other unchallenged provisions" of the law).

2. Plaintiffs' Claims Are Not Ripe.

The doctrine of ripeness is designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 807-08 (2003) (citation and quotation marks omitted). In determining whether a case is ripe for review, a court must evaluate both "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967).

Plaintiffs' pre-enforcement claims do not satisfy the "fitness" criterion of the ripeness analysis because they do not raise purely legal issues. *See id.* at 149 (holding that a claim is fit for review only where "the issue tendered is a purely legal one," and no "further administrative proceedings are contemplated"). Rather, plaintiffs seek an advisory opinion from this Court on mixed legal and factual issues, among them whether the many different actions purportedly taken by plaintiffs to obtain unpasteurized milk from unidentified sources in numerous states would violate FDA's regulations. Only in the context of a specific enforcement action will FDA have

gathered the necessary evidence and made the requisite administrative determinations to permit meaningful judicial review. *See Pub. Water Supply Dist. No. 8 v. City of Kearney*, 401 F.3d 930, 932 (8th Cir. 2005) ("The ripeness doctrine . . . prohibits us from issuing . . . an opinion advising what the law would be upon a hypothetical state of facts.").

Plaintiffs posit a number of *possible* interpretations of FDA's regulations that they contend *could* render their purported conduct unlawful, but they do not show that FDA has ever adopted such interpretations or ever used them as the basis for an enforcement action. Am. Compl. ¶¶ 78, 89-90, 129-130, 144. In *National Right to Life PAC v. Connor*, the Eighth Circuit Court of Appeals found that "additional factual development" was necessary to "be sure there [was] even a dispute" where the statute at issue was "nearly 25 years old" and the agency had "never" applied it in an unconstitutional manner. 323 F.3d 684, 694 (8th Cir. 2003). The regulations challenged here, 21 C.F.R. §§ 131.110 and 1240.61, have been in effect for thirty-seven and twenty-three years, respectively. Thus, in the absence of an actual enforcement action applying these regulations, plaintiffs' claims are unfit for judicial review because they "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998).

Plaintiffs' claims also fail to 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].'" *Public Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 573 (8th Cir. 2003)

(holding that an "'abstract injury is not enough'") (quoting *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974)). As discussed above, plaintiffs do not allege that FDA has taken any enforcement action against plaintiffs or others similarly situated or has even threatened by Warning Letter to take such action. *See BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 974 (D. Ariz. 2009) (dismissing a case on ripeness grounds where "FDA has not taken any enforcement actions with respect to companies, including [the plaintiff] . . . . Nor has the FDA taken the lesser action of issuing a warning letter to [the plaintiff] or to other similar companies"). Although plaintiffs "need not wait until the threatened injury occurs," their unsubstantiated fear of a possible enforcement action at some point in the future based on their conjectural interpretation of FDA's regulations falls far short of a "'certainly impending'" injury that merits judicial review. *Paraquad, Inc. v. St. Louis Hous. Auth.*, 259 F.3d 956, 958-59 (8th Cir. 2001) (quoting *Babbitt*, 442 U.S. at 298).

In contrast, FDA has a strong institutional interest in having this Court withhold review. If any person who could construe an FDA regulation in a manner that was unconstitutional or in excess of the agency's statutory authority could bring suit against FDA, then FDA—and the courts—would be required to devote a substantial proportion of their resources to litigate—and decide—those hypothetical cases. Dedicating scarce judicial and agency resources to theoretical disputes would necessarily leave the courts with less time to resolve actual cases and leave FDA to devote less time to protecting the public health. Thus, considering the hardships to the parties, this Court should decline to consider plaintiffs' challenges in the absence of an actual FDA enforcement action.

3. *Ewing* Establishes that FDA Enforcement Action May Not Be Enjoined.

"Plaintiffs seek to enjoin enforcement of [21 C.F.R. §§ 131.110 and 1240.61] against them by [FDA] and also seek a declaration that [the regulations] are unconstitutional as applied against them." Am. Compl. ¶ 2. Such relief is foreclosed by the Supreme Court's holding in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), wherein the plaintiff sought judicial review of FDA's determination that there was probable cause to believe that the plaintiff's products violated the FDCA—a necessary prerequisite to the government initiating a seizure of the products under the FDCA. The Supreme Court ruled that the district court lacked jurisdiction to review FDA's pre-seizure probable cause determination because "[j]udicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA]" envisioned by Congress in enacting the statute. *Id.* at 600-01 (observing that the plaintiff would have ample opportunity to litigate any constitutional, statutory, or factual claims in the enforcement action itself).

The Supreme Court reaffirmed the *Ewing* principle in *Abbott Laboratories v. Gardner*, calling it "clearly correct." 387 U.S. at 147. As the Court observed, the "manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the [FDCA]." *Id.* at 148. The rule articulated in *Ewing* has been "consistently and strictly observed" by the lower courts, which have held that the decision "precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context." *United States v. Alcon Labs.*, 636

F.2d 876, 881-82 (1st Cir. 1981); *see also Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 764 n.10 (5th Cir. 1980) (explaining that *Ewing* "expresses a total and complete proscription of the district court's power both to undertake a pre-enforcement review . . . and to enjoin federal officials from . . . seizing products or initiating enforcement proceedings under the [FDCA]"); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200, 1205-06 (6th Cir. 1977) (reversing, on *Ewing* grounds, a district court's injunction against FDA).

If FDA *were* to determine that plaintiffs' alleged conduct violated FDA's regulations prohibiting the interstate sale and distribution of unpasteurized milk, the government would have the discretion under the FDCA to initiate a seizure or injunction. *See* 21 U.S.C. §§ 332 and 334. At such a time, plaintiffs would have the opportunity to raise and litigate the claims that they advance in the present action. But plaintiffs' present request for this Court to enjoin all such future enforcement action is plainly foreclosed by *Ewing* and its progeny.

B. Plaintiffs Fail To State A Claim Upon Which Relief Can Be Granted.

Even if plaintiffs had standing to pursue this action, their claims would still fail because, as a matter of law, FDA's regulations do not represent an impermissible delegation of legislative authority, nor do they infringe upon plaintiffs' constitutional right to travel. And plaintiffs' assertion of a new "fundamental right" under substantive due process to produce, obtain, and consume unpasteurized milk lacks any support in law. Where, as here, "the allegations show on the face of the complaint that there is some insuperable bar to relief, dismissal under Rule 12(b)(6) is appropriate." *Benton v. Merrill Lynch & Co., Inc.*, 524 F.3d 866, 870 (8th Cir. 2008).

1. Plaintiffs Have Failed to Exhaust Their Administrative Remedies.

It is well established that an exhaustion of administrative remedies is generally required before proceeding to federal court. *See Bowen v. New York*, 476 U.S. 467, 484 (1986). In addition, the APA authorizes judicial review only with respect to "final agency action," 5 U.S.C. § 704, and an "agency action is final for the purposes of [the APA]" only after a plaintiff "has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 147 (1993) (quotation marks omitted). Nevertheless, plaintiffs have made no attempt to avail themselves of, much less exhaust, the administrative remedy available to them—filing a citizen petition with FDA pursuant to 21 C.F.R. §§ 10.25 and 10.30. FDA regulations require that "before any legal action is filed in a court," a party must first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of administrative action." *Id.* § 10.45(b). FDA's response to such a petition constitutes final agency action subject to immediate judicial review under the APA. *Id.* § 10.45(d).

Plaintiffs' failure to use available administrative remedies has prevented FDA from developing the factual issues in this matter and applying the agency's own interpretation of its regulations to those facts, including whether: (1) plaintiffs "sell" or "distribute" unpasteurized milk "into interstate commerce," in violation of 21 C.F.R. § 1240.61, when they buy such products for their personal consumption or share them among members of a "virtual farmer's market;" or (2) the crossing of state lines with unpasteurized milk that does not comply with the milk standard of identity, 21 C.F.R. § 131.110, constitutes the "introduction or delivery for introduction of a misbranded food

into interstate commerce," 21 U.S.C. § 331(a), where the unpasteurized milk at issue is intended for personal consumption.

In bypassing the administrative process, plaintiffs have precluded meaningful and efficient judicial review. Requiring plaintiffs to submit a citizen petition to FDA before seeking judicial review would allow FDA to consider and address plaintiffs' concerns and could potentially resolve those concerns, or at the very least, the administrative process might crystalize the issues in contention. *See Parisi v. Davidson*, 405 U.S. 34, 37 (1972) ("The 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."). Because plaintiffs have failed to avail themselves of the administrative process, dismissal of this action is appropriate. *See Ass'n of Am. Physicians & Surgs., Inc. v. FDA*, 539 F. Supp. 2d 4, 22 (D.D.C. 2008) (dismissing APA and constitutional claims under Rule 12(b)(6) where the plaintiffs neglected to file a citizen petition as "mandated" by FDA's regulations), *aff'd*, No. 08-5458, 2009 WL 5178484 (D.C. Cir. Nov. 27, 2009).

2. FDA's Regulations Do Not Violate the Non-Delegation Doctrine Nor Do They Exceed FDA's Statutory Authority.

Plaintiffs argue that FDA's regulations prohibiting the interstate sale and distribution of unpasteurized milk for human consumption "violate the separation of powers/non-delegation doctrine because only Congress, not the FDA, has the authority to enact legislation that restricts the personal liberty of persons who wish to consume raw milk." Am. Compl. ¶ 130; *see also id.* ¶¶ 126-129 (insisting that "there is nothing in the PHSA [or FDCA] that authorizes FDA to" promulgate the regulations). In advancing

this claim, plaintiffs appear to be confusing the non-delegation doctrine with Section 706(2)(C) the APA, which permits courts to set aside agency regulations promulgated "in excess of statutory jurisdiction [or] authority." Constitutional non-delegation claims are appropriately leveled at congressional enactments that impermissibly delegate lawmaking authority, not *ultra vires* agency regulations. *See Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 876-77 (9th Cir. 2003) (evaluating a non-delegation claim and observing that "[t]he relevant question is not whether [the agency]'s interpretation is unconstitutional, but whether the statute itself is unconstitutional") (citing *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 473 (2000)).

Nowhere in their Amended Complaint do plaintiffs contend that Congress's enactment of the PHSA and FDCA imposed "[in]sufficient standards upon FDA to satisfy the constitutional requirements of the nondelegation doctrine." *United States v. Garfinkel*, 29 F.3d 451, 457 (8th Cir. 1994) (explaining that where Congress "'legislates in broad terms, leaving a certain degree of discretion to [an agency,] . . . such legislative action is not a forbidden delegation of legislative power . . . [s]o long as Congress lays down by legislative act an intelligible principle to which the [agency] is directed to conform'") (quoting *Touby v. United States*, 500 U.S. 160, 164-65 (1991)) (add'l citation omitted). Nor could plaintiffs reasonably so allege because both the PHSA and FDCA contain sufficient language to set forth an "intelligible principle" to constrain FDA's discretion. Under the PHSA, the Commissioner may promulgate only those regulations that "are necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 U.S.C. § 264(a). And, the Commissioner may promulgate a food standard of identity under the FDCA only where doing so will

"promote honesty and fair dealing." 21 U.S.C. § 341. Such language is "sufficiently specific and detailed to meet constitutional requirements." *Mistretta v. United States*, 488 U.S. 361, 374 (1989)*; see also Touby*, 500 U.S. at 165 (observing that the Supreme Court has "upheld as providing sufficient guidance statutes authorizing [agencies] to recover 'excessive profits,' . . . fix 'fair and equitable' commodities prices," and "regulate broadcast licensing in the 'public interest'").

Plaintiffs' contentions regarding the non-delegation doctrine are more appropriately cast as an *ultra vires* claim under the APA. *See* 5 U.S.C. § 706(2)(C); Am. Compl. ¶ 124 (arguing that "[t]he rulemaking power granted to an administrative agency . . . is not the power to make laws"). Plaintiffs' APA argument is also unavailing, however, because the challenged regulations were promulgated by FDA in obedience to explicit statutory mandates, and FDA's determination that such regulations are necessary is entitled to deference. *See Niobrara River Ranch, LLC v. Huber*, 373 F.3d 881, 884 (8th Cir. 2004) (cautioning the courts to be "[m]indful of our narrow standard of review and the deference we must afford to agency decisions" in evaluating a challenge under 5 U.S.C. § 706(2)(C)).

FDA's regulation prohibiting the interstate sale or distribution of unpasteurized milk, 21 C.F.R. § 1240.61, was promulgated pursuant to 42 U.S.C. § 264(a), which authorizes FDA to issue regulations to prevent the introduction, transmission, and spread of communicable diseases between the states. FDA was ordered to promulgate this regulation by the court in *Public Citizen II*, after the court reviewed evidence before FDA showing that unpasteurized milk contributed to the spread of communicable diseases, including campylobacteriosis and salmonellosis. 653 F. Supp. 1229; *see also*

Public Citizen I, 602 F. Supp. at 613 ("Under both the [PHSA]'s authorization for regulations to control communicable diseases, 42 U.S.C. § 264, and the [FDCA] . . . , the Secretary has both the authority and the heavy responsibility to act to protect the nation's health in situations such as this one.").

Similarly, the milk standard of identity, 21 C.F.R. § 131.110, was issued pursuant to 21 U.S.C. § 341 of the FDCA, which directs FDA to issue "a reasonable definition and standard of identity" "for any food" where "in the judgment of the [Commissioner] such action will promote honesty and fair dealing in the interest of consumers." This regulation, as recognized by the court in *Shamrock Farms*, was "designed to inform consumers about the content of the milk they purchase and to protect against fraud and misrepresentation." 146 F.3d at 1178. Its promulgation was an appropriate exercise of the considerable discretion conferred by Congress upon FDA. Accordingly, plaintiffs' challenge to FDA's regulations, whether evaluated under either the constitutional non-delegation doctrine or the APA, is without merit.

3. FDA's Regulations Do Not Implicate the Constitutional Right to Travel.

Plaintiffs contend that they "have a fundamental right to travel from one State to another State in a manner that is free from unnecessary burdens." Am. Compl. ¶ 104. Essentially, plaintiffs assert that they have a right to travel across state lines *with* unpasteurized milk. The Constitution recognizes no such right, however.

"Although the word travel is not found in the Constitution, the Supreme Court has frequently recognized 'the constitutional right to travel from one State to another.'" *Minn. Senior Fed'n v. United States*, 273 F.3d 805, 809 (8th Cir. 2001) (quoting *Saenz v. Roe*, 526 U.S. 489, 498 (1999)). The right to travel encompasses three different

components: (1) "the right to go from one place to another, including the right to cross state borders while en route;" (2) the right of "a citizen of one State who travels in other States, intending to return home at the end of his journey, . . . to enjoy the 'Privileges and Immunities of Citizens in the several States' that he visits;" and (3) "the right of the newly arrived citizen to the same privileges and immunities enjoyed by other citizens of the same State." *Saenz*, 526 U.S. at 500-02 (citations and quotation marks omitted). The constitutional right to travel is appropriately used to strike down "state legislation that had a negative impact on travel between the various States," but is inapposite in attacking "a federal statutory regime because it allegedly deters interstate travel." *Minn. Senior Fed'n v. United States*, 273 F.3d at 810 (noting that the later "contention is clearly too broad" and "finds no support in the Supreme Court's right-to-travel cases").

Unquestionably, FDA's regulations prevent individuals from introducing unpasteurized milk into interstate commerce, but they in no way affect the ability of individuals to travel from one state to another, to be subject to the same laws as citizens of a state in which they are visiting, or for those moving to a new state to be to be subject to the same laws as the citizens already residing there. "[T]o recognize a fundamental right to interstate travel in a situation that does not involve any of these circumstances would extend the doctrine beyond the Supreme Court's pronouncements in this area." *Doe v. Miller*, 405 F.3d 700, 712 (8th Cir. 2005); *see also Monson v. DEA*, 589 F.3d 952, 963 (8th Cir. 2009) (holding that it is "well-established" that under the Commerce Clause "Congress is permitted to regulate purely local activities that . . . have a substantial effect on interstate commerce"). Accordingly, plaintiffs' claim that

the constitutional right to travel encompasses the right to travel with unpasteurized milk must fail.

4. FDA's Regulations Do Not Infringe Upon Substantive Due Process Rights.

Plaintiffs contend that FDA's regulations violate certain "fundamental rights" purportedly protected by the Due Process Clause of the Fifth Amendment: (1) the "fundamental right to raise their famil[ies] in their own way, which includes what foods they do and do not choose to consume for themselves and their families;" (2) the "fundamental right to their own bodily and physical health, which includes what foods they do and do not choose to consume for themselves and their families;" and (3) fundamental "contract rights" to "the use of an agent to accomplish what the principal herself ought to be free to do," which includes having "raw milk . . . transported across State lines by an agent." Am. Compl. ¶¶ 117-118, 135, 143-144.

"In evaluating this argument, it is important to consider the Supreme Court's admonition that 'substantive due process analysis must begin with a careful description of the asserted right, for the doctrine of judicial self-restraint requires us to exercise the utmost care whenever we are asked to break new ground in this field.'" *Doe*, 405 F.3d at 710 (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)) (add'l citation and quotation marks omitted). One reason for judicial restraint in this area is that "[b]y extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action." *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997); *see also Collins v. Harker Heights*, 503 U.S. 115, 125 (1992) ("[T]he Court has always been reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking in this

unchartered area are scarce and open-ended."). Thus, the Supreme Court has established demanding criteria for the recognition of fundamental rights; a plaintiff must show both that the rights claimed "are, objectively, deeply rooted in this Nation's history and tradition . . . and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed." *Glucksberg*, 521 U.S. at 720-21 (citation and quotation marks omitted). Plaintiffs fall far short of satisfying these criteria.

a. There is No Absolute Right to Consume or Feed Children Any Particular Food.

Although "[t]wo of the earliest right to privacy cases," *Meyer v. Nebraska*, 262 U.S. 390 (1923), and *Pierce v. Society of Sisters*, 268 U.S. 510 (1925), "established the existence of a fundamental right to make child rearing decisions free from unwarranted governmental intrusion," these cases do not "establish an absolute parental right to make decisions relating to children free from government regulation." *Henne v. Wright*, 904 F.2d 1208, 1214 (8th Cir. 1990) (citing *Prince v. Massachusetts*, 321 U.S. 158 (1944)). Plaintiffs' generalized assertion of "fundamental privacy rights of raising their families in the way they see fit," Am. Compl. ¶ 120, falls far short of the "careful description of the asserted right" that forms the starting point of the "established method of substantive-due-process analysis." *Glucksberg*, 521 U.S. at 720-21. Here, plaintiffs' "characterization of a fundamental right to 'personal choice regarding the family' is so general that it would trigger strict scrutiny of innumerable laws and ordinances that influence 'personal choices' made by families on a daily basis." *Doe*, 405 F.3d at 710; *see also Henne*, 904 F.2d at 1214 (upholding a restriction on parents' choice of surnames for children that allegedly violated the broad right to make "parental decisions relating to child rearing").

The interest claimed by plaintiffs could be framed more narrowly as a right to "provid[e] them[selves] and their families with the foods of their own choice." Am. Compl. ¶ 120. But there is no "deeply rooted" historical tradition of unfettered access to food of all kinds. *See Glucksberg*, 521 U.S. at 721. To the contrary, society's long history of food regulation stretches back to the dietary laws of biblical times. *See* Peter Barton Hutt & Peter Barton Hutt II, *A History of Gov't Regulation of Adulteration & Misbranding of Food*, 39 Food, Drug & Cosmetic Law J. 2, 3 (1984) (citing *Leviticus* 11, 17 and 19, and *Deuteronomy* 14). Modern food safety regulation in the United States has its roots in the early food laws of the American colonies, which themselves incorporated "the tradition of food regulation established in England." *Id.* at 35; *see also id.* at 43 (citing a Virginia statute passed in 1873, that "made it an offense . . . [to] knowingly, sell, supply, or bring to be manufactured . . . milk from which any cream has been taken; or milk commonly known as skimmed milk"). Comprehensive federal regulation of the food supply has been in effect at least since Congress enacted the Pure Food and Drugs Act of 1906, and was strengthened by the passage of the FDCA in 1938. Thus, plaintiffs' claim to a fundamental privacy interest in obtaining "foods of their own choice" for themselves and their families is without merit. Am. Compl. ¶ 120.

b. There is No Generalized Right to Bodily and Physical Health.

Plaintiffs' assertion of a "fundamental right to their own bodily and physical health, which includes what foods they do and do not choose to consume for themselves and their families" is similarly unavailing because plaintiffs do not have a fundamental right to obtain any food they wish. In addition, courts have consistently refused to extrapolate a generalized right to "bodily and physical health" from the

Supreme Court's narrow substantive due process precedents regarding abortion, intimate relations, and the refusal of lifesaving medical treatment. *See Glucksberg*, 521 U.S. at 721 (warning that the fact "[t]hat many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected"); *see also Cowan v. United States*, 5 F. Supp. 2d 1235, 1242 (N.D. Okla. 1998) (rejecting a claim that the plaintiff had the fundamental "right to take whatever treatment he wishes due to his terminal condition regardless of whether the FDA approves the treatment"). Finally, even if such a right did exist, it would not render FDA's regulations unconstitutional because prohibiting the interstate sale and distribution of unpasteurized milk promotes "bodily and physical health."

c. There is No Fundamental Right to Freedom of Contract.

In arguing that FDA's regulations violate substantive due process because they interfere with plaintiffs' "contract rights" by "restricting the use of an agent to accomplish what the principal herself out to be free to do," plaintiffs ask this Court to resuscitate long-dead, *Lochner*-era jurisprudence. *See Ferguson v. Skrupa*, 372 U.S. 726, 729 (1963) ("There was a time when the Due Process Clause was used by this Court to strike down laws which were thought . . . incompatible with some particular economic or social philosophy," but that doctrine "has long since been discarded."). Plaintiffs' anachronistic invitation should be rejected.

5. FDA's Regulations Rationally Advance the Agency's Public Health Mission.

Because the interests asserted by plaintiffs are not fundamental rights, FDA's regulations are not subject to strict scrutiny. Instead, plaintiffs have the burden of

showing that the regulations do not bear a rational relationship to legitimate governmental interests. *See Heller v. Doe*, 509 U.S. 312, 319 (1993). Under rational basis review, FDA's regulations are presumed to be constitutional, and "must be upheld . . . if there is any reasonably conceivable state of facts that could provide a rational basis" for them. *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993); *see also id.* at 315 ("[A] legislative choice is not subject to courtroom factfinding and may be based on rational speculation unsupported by evidence or empirical data.").

Plaintiffs argue that "FDA could use a less stringent means of regulating raw milk," such as warning labels stating that the products are unpasteurized. Am. Compl. ¶¶ 79-81, 105-108. In promulgating 21 C.F.R. § 1240.61, FDA specifically considered "the use of labeling to ensure that consumers who voluntarily choose to consume raw milk are informed as to the risks inherent in that choice," but FDA concluded, for reasons it explained, "that labeling is not an acceptable alternative approach." 52 Fed. Reg. at 29,513 (explaining that "the risk of infection . . . does not arise from the misuse or abuse of the product but rather from its customary food use," and those who "are particularly susceptible to serious risks of infection," including the elderly and children, "may not have the ability or the opportunity to understand the risks identified in labeling"). FDA could have also prohibited intrastate sales but concluded "that State and local authorities may be better situated to deal with the public health problems attributable to unpasteurized milk." *Id.* Whether FDA used the least restrictive means to accomplish its goal, however, is immaterial under a rational basis review. *See Heller*, 509 U.S. at 330 (holding that whether a less restrictive means exists to further the legislative aims "is irrelevant in rational-basis review").

FDA's goals in regulating the interstate sale and distribution of unpasteurized milk are manifestly appropriate, and the regulations that FDA adopted are an undeniably rational way of pursuing them. The task of making those judgments is one that the Constitution assigns to the political branches, not the courts. *See Doe*, 405 F.3d at 715-16 ("The legislature is institutionally equipped to weigh the benefits and burdens of various [restrictions], and to reconsider its initial decision in light of experience and data accumulated over time.").

V. CONCLUSION

For all of the foregoing reasons, plaintiffs' Amended Complaint is without legal basis. Defendants respectfully request that this Court dismiss this case for lack of jurisdiction over the subject matter or, in the alternative, failure to state a claim upon which relief can be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I electronically served a copy of the foregoing document to which this certificate is attached to the parties or attorneys of record, shown below, on April 26, 2010.

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