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.	)	

DEFENDANTS' BRIEF IN RESISTANCE TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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In 1987, based on an 18,800 page administrative record demonstrating the public health risks of unpasteurized milk, the United States Food and Drug Administration ("FDA") promulgated 21 C.F.R. § 1240.61 (the "PHSA Regulation") prohibiting the delivery of raw milk into interstate commerce. In promulgating the PHSA Regulation, FDA concluded that the administrative record demonstrated an "association between the consumption of raw milk and the outbreak of disease." *See* Requirements Affecting Raw Milk for Human Consumption, 52 Fed. Reg. 29511 (August 10, 1987) ("Final Rule"). Nearly twenty-five years later, without FDA having brought or even threatened any enforcement action against any of the plaintiffs, they filed this suit challenging the PHSA Regulation seeking to establish, *inter alia*, novel constitutional rights to travel in interstate commerce with raw milk. Plaintiffs also seek to invalidate the standard of identity for milk, 21 C.F.R. § 131.110 (the "Milk Standard of Identity Regulation"), which has been in effect for nearly forty years, but has *never* been relied upon by FDA in any raw milk-related enforcement action. As explained previously, plaintiffs' arguments are wholly without merit and their attempt to add to the list of fundamental rights protected by the Constitution should be rejected. *See* Brief in Support of Defendants' Renewed Motion to Dismiss Plaintiffs' Amended Complaint, and, in the Alternative, for Summary Judgment; and Brief on the Merits In Support of FDA's Promulgation of the Challenged Regulations, filed on May 5, 2011 (DR[1] 51) ("Combined Brief").

The procedural history of this matter is set forth in defendants' Combined Brief. Combined Br. at 4-6. In their Combined Brief, defendants also presented three distinct reasons why plaintiffs' claims are without merit and this litigation should now end.

[1] "DR" refers to the docket report.

First, defendants demonstrated that plaintiffs' claims, which were brought at least twenty-three years following the challenged final agency action, are barred by the statute of limitations. *See* Combined Br. at 11-22. This argument was the sole issue presented in the form of a narrowly focused motion for summary judgment.

Second, defendants showed the promulgation of the PHSA Regulation was neither arbitrary and capricious, nor contrary to law. *See* Combined Br. 23-38. In addition, with respect to the Milk Standard of Identity Regulation, defendants showed plaintiffs' claims are not justiciable because that regulation has never been relied upon in any enforcement action involving raw milk.

Third, defendants supplemented their motion to dismiss plaintiffs' constitutional claims because not a single case recognizes the exotic rights that plaintiffs seek to have this Court establish. Indeed, plaintiffs admit their claims are novel and perhaps unprecedented. *See* Combined Br. at 42 (citing Pls.' Resist. to Defs.' Motion to Dismiss at 3 (DR 17)).

Plaintiffs filed a Brief in Support of Resistance to Defendants' Revised Motion to Dismiss and Motion for Summary Judgment (DR 61) ("Resistance") and a Brief in Support of Summary Judgment (DR 57) ("Summary Judgment Brief") (hereinafter, collectively, the "Briefs"). Because plaintiffs' Briefs are nearly identical, in the interests of efficiency and brevity, and with one exception, defendants' response to both is as set forth below. Because the statute of limitations issues are not relevant to issues raised in plaintiffs' Summary Judgment Brief, defendants' further arguments on this point are set forth in the accompanying Reply in Support of Defendants' Motion for Summary Judgment.

As detailed below, plaintiffs' Briefs raise a series of frivolous arguments that do not survive their own articulation. For example, plaintiffs argue their trips to other states to buy milk and re-cross state lines do not constitute interstate commerce. Plaintiffs argue Section 361(a) of the Public Health Service Act (42 U.S.C. § 264(a)) ("PHSA"), has nothing to do with the regulation of interstate commerce, even though the PHSA expressly provides it is intended to help control the *interstate* introduction, transmission, or spread of disease. Plaintiffs also argue, again, in the face of clear statutory language to the contrary, the government's regulation of milk delivered in interstate commerce has no rational relation to any legitimate governmental interest. These, and the remainder of plaintiffs' equally unavailing arguments, are addressed below.

I. The Regulations are Neither Arbitrary Nor Contrary to Law.

A. The Evidence in the Administrative Record Provided Ample Justification for Promulgating the PHSA Regulation.

Despite the fact FDA amassed an extensive administrative record demonstrating a clear association between the consumption of raw milk and the outbreak of disease, plaintiffs ignore the administrative record altogether. *See* Pls.' Resist. at 3 ("[T]he administrative record in this case and the basis for adopting [§§] 1240.61 and 131.110 have nothing to do with plaintiffs' claims in this case."). In so arguing, plaintiffs have conceded the scientific evidence compiled by defendants demonstrates conclusively the dangers of consuming raw milk. There is no real dispute pasteurization and other modern sanitation techniques have saved hundreds of lives and helped avoid tens of thousands of illnesses over the years. *See* Combined Br. at 29-37; *see also Public Citizen v. Heckler*, 653 F. Supp. 1229, 1238 (D.D.C. 1986) ("*Public Citizen II*") ("[O]verwhelming evidence of the risks associated with the consumption of raw milk,

both certified and non-certified, has been presented."). Furthermore, in light of the administrative record, there can be no serious question FDA's promulgation of the PHSA Regulation was eminently reasonable. As discussed in the Combined Brief, the standard under the APA is whether the agency's "decision was based on a consideration of the relevant factors and . . . there has been [no] clear error of judgment." Combined Br. at 23 (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971)). At a minimum, the agency must have considered the relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Id.* at 23-24 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)). FDA satisfied this standard by reaching an indisputably-reasoned conclusion that raw milk was dangerous and describing the bases for its conclusions in the Final Rule. *See* Combined Br. 29-39; *see also* 52 Fed. Reg. 29511 (the record "reasonably demonstrate[d] an association between the consumption of raw milk and the outbreak of disease.").

Plaintiffs' claim the PHSA Regulation is arbitrary and capricious because FDA did not consider s*ome* raw milk producers *may* be dedicated to maintaining sanitary conditions has no merit. *See* Pls.' Resist. at 51 ("FDA's record does not address the other way that raw milk is processed, a process so completely different from the typical raw milk operation that the milk is intended to be consumed in its fresh, unprocessed, raw state."). Here, too, plaintiffs are wrong. FDA concluded in the Final Rule careful production of raw milk *does not* eliminate the public health threat. *See* Combined Br. at 36 (quoting 52 Fed. Reg. 29512 ("[r]aw milk, no matter how carefully produced, may be unsafe" and careful production practices or certification processes alone "provide no

assurance that raw milk is free of *Salmonella* and other harmful organisms")). FDA *specifically considered* and *rejected* plaintiffs' idea that good farming practices can lead to safe raw milk.

Although plaintiffs like to quote Hippocrates (from the 5th century B.C.) as saying food is medicine (*see, e.g.*, Pls.' Summ. J. Br. at 29), the record does not support the view that raw milk has medicinal qualities. In the Final Rule, FDA reasonably concluded there are no demonstrable health benefits from drinking raw milk. *See* Combined Br. at 36-37. Moreover, even if there were some factual bases for the belief that raw milk provides health benefits, "FDA concluded that the dangers posed by raw milk 'outweigh any alleged health benefits that may arise from consuming raw milk and certified raw milk.'" *Id.* at 37 (quoting 52 Fed. Reg. at 29512-13).

Finally, plaintiffs' argument the PHSA Regulation is arbitrary and capricious because warning labels "would provide just as much protection" as pasteurization (*see* Pls.' Summ. J. Br. at 24; Pls.' Resist. at 39) was also considered and specifically rejected by FDA in the Final Rule. *See* Combined Br. at 37-39. As FDA concluded, "the risk of infection from consuming raw milk and raw milk products does not arise from the misuse or abuse of the product but rather from its customary use." *Id.* at 37 (quoting 52 Fed. Reg. at 29513). Because customers are "not generally expected to take any additional steps to reduce the potential risk and are poorly equipped to assess the likelihood of infection," warning labels were appropriately deemed to be an inadequate alternative to pasteurization. *See id.*

B. Plaintiffs' Attempt to Supplement the Administrative Record Should Be Rejected.

Instead of addressing the contents of the administrative record, plaintiffs point to a thin collection of materials purportedly supporting the health benefits of drinking raw milk. *See* Pls.' Statement of Additional Material Facts in Support of Their Resistance to Defs.' Renewed Motion to Dismiss/For Summary Judgment; and Plaintiffs' Appendix in Resistance to FDA's Motion for Summary Judgment (DR 57), *cited* in Pls.' Briefs, *passim*. As discussed in defendants' Combined Brief, however, this material is not relevant to the Court's decision here, because "[i]t is well-established that judicial review under the APA is limited to the administrative record that was before the agency when it made its decision." Combined Br. at 24 (quoting *Voyageurs Nat. Park Ass'n. v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004)). "By confining judicial review to the administrative record, the APA precludes the reviewing court from conducting a de novo trial and substituting its opinion for that of the agency." *Voyageurs*, 381 F.3d at 766.

Plaintiffs argue this Court should consider their extra-record submissions because the administrative record "is archaic" (*see* Pls.' Resist. at 3), but plaintiffs cannot fairly criticize the age of the record when it is they who challenge a 25 year-old rule. More importantly, because the administrative record contains the materials before the Agency when it promulgated the PHSA Regulation, there is no basis for supplementing the record now. Only under "extraordinary circumstances" involving "bad faith or improper behavior" might extra-record evidence be admitted where the Agency has produced a contemporaneous administrative record. *See Voyageurs*, 381 F.3d at 766. Such circumstances are plainly not present, and thus plaintiffs have failed

to carry their burden in demonstrating an established exception justifies consideration of extra-record materials.[2]

The improper purpose behind plaintiffs' extra-record submissions is underscored by their attempt to use them to create a "dispute of fact."[3] *See, e.g.*, Pls.' Resist. at 51 ("[A]t a minimum, the evidence submitted by Plaintiffs . . . creates a genuine issue of material fact . . . ."). As courts in this district have recognized, the summary judgment paradigm "makes no procedural sense" in APA cases (*see, e.g.*, *Thomas v. E.P.A.*, No. 06-CV-115-LRR, 2007 WL 2127881, *1 (N.D. Iowa July 23, 2007)), and the local rules specify summary judgment procedures do not apply in cases involving judicial review of an agency record.[4] *See* LR 56.i. APA review is confined solely to the administrative record and there is no room for "disputes of fact" or trials. *See Thomas*, 2007 WL 2127881, *1 (citing *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1579-80 (10th

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[2] The vast majority of the documents plaintiffs cite in support of their contention the administrative record fails to contain information regarding the health benefits of raw milk, and is therefore unreliable, were created after the issuance of the final rule. *See* Pls.' App. at 0105-110; 0111-15; 0116-17; 0118; 0119-28; 0129-37; 0138-39; 0140; 0151-53; 0154-55; 0213-16; 0217-26; 0227-31; and 0232-35. As a result, these documents are, by definition, not materials before the agency at the time it rendered its decision and therefore they are not part of the administrative record under review here. *See Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (letters criticizing agency decision written after the decision at issue are not part of the administrative record). If plaintiffs believe their recent evidence supports amending the regulation, the proper procedure is for them to petition the agency pursuant to 21 C.F.R. § 10.30. But they cannot argue FDA acted arbitrarily in 1987 based on materials not in existence at the time the rule was issued.

[3] Of course, at other places, plaintiffs admit there are *no* disputes of fact. *See* Pls.' Summ. J. Br. at 4 ("In this case, the material facts are not in dispute.").

[4] Defendants' motion for summary judgment is easily distinguishable, for it was limited to the statute of limitations issue involving undisputed factual issues (*i.e.*, whether plaintiffs' claims are facial or as-applied challenges). Defendants have *not* moved for summary judgment on the merits of plaintiffs' APA claims, but instead have briefed the APA issues on the merits in accordance with the local rules.

Cir. 1994) ("[The summary judgment] process, at its core, is inconsistent with the standards for judicial review of agency action under the APA."); *Phoenix-Griffin Group II, Ltd. v. Chao*, 376 F. Supp. 2d 234, 245 (D.R.I. 2005) ("A motion for summary judgment . . . makes no procedural sense when a district court is asked to undertake judicial review of administrative action."); *Lodge Tower Condo. Ass'n v. Lodge Props.*, *Inc.*, 880 F. Supp. 1370, 1374 (D. Colo. 1995) ("Agency action . . . is reviewed, not tried.")).

C. FDA Did Not Deem Raw Milk to be a Communicable Disease *Per Se*.

Plaintiffs next argue FDA's promulgation of the PHSA Regulation was arbitrary and capricious because the Agency deemed raw milk to be "a communicable disease *per se.*" *See, e.g.*, Pls.' Summ. J. Br. at 15-17. But as we have explained, "the PHSA provides authority to promulgate regulations 'to prevent the introduction, transmission, or spread of communicable diseases.' 42 U.S.C. § 264(a). FDA has not deemed the milk itself to be a 'communicable disease' but FDA *has* decided that raw milk should be regulated to help deter the *spread* of communicable diseases." Combined Br. at 52 (citing 52 Fed. Reg. 29509, 29511). Acceptance of plaintiffs' theory the PHSA does not allow the government to regulate known disease vectors such as raw milk would eviscerate Congress' intent to protect public health, for the ability to "prevent the introduction, transmission, or spread of communicable diseases" (*see* 42 U.S.C. § 264(a)), depends in large part the ability to regulate the carriers of such diseases (such as, for example, infected animals, commodities, and even persons).

Plaintiffs' contention the PHSA does not provide for the regulation of articles such as raw milk conflicts with the plain language of the statute, which provides FDA with broad authority to both promulgate rules as "necessary to prevent . . . the spread of

communicable diseases," and to carry out and enforce such regulations through any "other measures as in [FDA's] judgment may be necessary." *Id.* Even without the benefit of the liberal construction afforded to public health statutes, *see United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), this language plainly authorizes the government to regulate the interstate transportation of articles that are known to carry and spread communicable diseases. *See also Louisiana v. Matthews*, 427 F. Supp. 176 (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.").

D. Plaintiffs' Claims Regarding the Milk Standard of Identify Regulation Are Frivolous and Not Ripe.

Plaintiffs' argument the nearly 40-year-old Milk Standard of Identity Regulation has "no relationship to honesty and fair dealing" also lacks merit. *See, e.g.*, Pls.' Summ. J. Br. at 18-20. As discussed in the Combined Brief, 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."[5] 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

[5] 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.

healthy cows" that "in final package form for beverage use shall have been pasteurized or ultrapasteurized." *See* 21 C.F.R. § 131.110(a). 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).

Plaintiffs presume that raw milk, labeled as such, could never implicate honesty and fair dealing, but they misapprehend the policies behind the statute. As the Supreme Court discussed in *Fed. Sec. Adm'r v. Quaker Oats Co.*, "the 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." 318 U.S. 218, 232 (1943) (emphasis added). Congress' goal in enacting 21 U.S.C. § 341 was thus to provide for the standardization of certain foods sold under a common or usual name, so that consumers can be sure of what they are buying. Under *Quaker Oats Co.*, the sale of even a truthfully labeled version of a non-standard food could undermine Congress' goal in providing certainty to customers.

In any event, as discussed in the Combined Brief, plaintiffs' claims with respect to the Milk Standard of Identity Regulation are not justiciable here because, to FDA's knowledge, the government has never initiated a single enforcement action with respect to the interstate distribution of raw milk based on a violation of the Milk Standard of Identity Regulation. *See* Combined Br. at 39-42. Nor has FDA cited the regulation in *any* of the Warning Letters that it has issued relating to the interstate distribution of raw

milk. *Id.* Since the promulgation of the PHSA Regulation in 1987, FDA has relied entirely on the PHSA Regulation to ensure that raw milk delivered into interstate commerce has been pasteurized, and the agency has no present intention to alter that practice. Plaintiffs have no response, except to say FDA's statement of its enforcement policy—the *raison d'être* of their suit—is a "red herring." *See* Pls.' Resist. at 52.[6]

Rather than being a red herring, the foregoing demonstrates plaintiffs' claims with respect to the Milk Standard of Identity Regulation are unripe, for they cannot plausibly claim they have sustained or are in immediate danger of sustaining any injury from the thirty-eight-year-old Milk Standard of Identity Regulation. *See* Memorandum Opinion and Order (DR 27) at 41 (ripeness requires a showing plaintiffs "have sustained or *are in immediate danger* of sustaining some direct injury as a result of the challenged statute or official conduct.").[7]

E. The Regulations Are Not *Ultra Vires.*

Plaintiffs assert "[the PHSA Regulation] goes beyond the reach of the FDA's authority under the FDCA." *See* Pls.' Summ. J. Br. at 12; Pls.' Resist. at 20. But of course, the PHSA Regulation was not promulgated under the FDCA. Plaintiffs even go so far as to allege, without citation, Congress "has expressly decided not to prohibit" the delivery of raw milk in interstate commerce. *See* Pls.' Resist. at 15. The authority for the PHSA Regulation, however, was amply described in the Combined Brief. *See*

[6] By arguing the interstate transportation of raw milk became illegal in 1987, plaintiffs appear to acknowledge the Milk Standard of Identity Regulation does not play any significant role in FDA's regulation of raw milk. *See* Pls.' Summ. J. Br. at 28 ("[I]t only became illegal to take raw dairy products across state lines as recently at 1987.").

[7] Similarly, plaintiffs have no response to defendants' argument the Milk Standard of Identity Regulation should not be subject to a challenge without plaintiffs presenting facts about actual labeling. *See* Combined Br. at 41.

Combined Br. at 27-29. As expressly stated in section 361(a) of the PHSA the "Surgeon General *is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases* [between states]." 42 U.S.C. § 264(a) (emphasis added). Furthermore, the PHSA provides a broad set of powers to enforce such regulations, including authorizing "inspection, fumigation, disinfection, sanitation, pest extermination, [and] destruction of animals or articles" and "other measures" that may be necessary. *Id.* This statutory language provides ample authority for the PHSA Regulation. *See Public Citizen v. Heckler*, 602 F. Supp. 611, 613 (D.D.C. 1985) ("*Public Citizen I*") (noting "the [PHSA]'s authorization for regulations to control communicable diseases" provided "ample legal authority" for FDA to institute the ban).

Plaintiffs also argue "nothing in the PHSA authorizes FDA to regulate 'interstate commerce'" (*see* Pls.' Summ. J. Br. at 36), but the PHSA authorizes regulations to prevent the transmission of disease, etc., *"from one State or possession into any other State or possession*." 42 U.S.C. § 264(a) (emphasis added).

Plaintiffs even argue the Regulations are *ultra vires* because they "are not rationally related to any legitimate public interest." *See* Pls.' Summ. J. Br. at 38. Congress has said otherwise. Section 361(a) authorizes the Government to act to prevent the "introduction, transmission, or spread of communicable disease," 42 U.S.C. § 264(a), and the nexus between the PHSA Regulation and preventing the spread of contagious disease is amply supported by the administrative record.

Finally, plaintiffs are wrong in arguing the PHSA Regulation is *ultra vires* because of misplaced Agency "reliance" on *Public Citizen.* First, although FDA indeed acted in

accordance with the Court's order, following the notice and comment rulemaking process through which the PHSA Regulation was promulgated, FDA ultimately agreed "the use of Federal authority and resources to eliminate health problems caused by the interstate shipment of raw milk is justifiable." 52 Fed. Reg. at 29513.

Moreover, as FDA discussed in the Final Rule, there was never any dispute between the Agency and the Court over the dangers of raw milk—only over the best way to address those dangers: "[t]he difference in viewpoint between the agency and the Court and comments received has concerned the appropriate way to use Federal resources and the level of government that is best suited to dealing with problems created by raw milk, not the fact that unpasteurized milk and milk products present health risks." 52 Fed. Reg. at 29513. Following the notice and comment rulemaking process, however, the Agency announced its "belie[f] that a final rule requiring the pasteurization of all raw milk and raw milk products in interstate commerce should issue . . . ." *Id.* Through the rulemaking process, FDA's and the *Public Citizen II* court's views were harmonized, and today, FDA fully supports the policy goals embodied in the PHSA Regulation.[8]

II. Plaintiffs Are Engaged in Interstate Commerce.

In their Briefs, plaintiffs argue their purchases and sales of raw milk do not implicate interstate commerce, and they are thus immune from the Regulations. This

[8] The notice and comment rulemaking process also obviates plaintiffs' concern the *Public Citizen II* court ordered a ban of interstate raw milk "sales," while FDA decided to prohibit the delivery of raw milk into interstate commerce altogether. Even if the *Public Citizen II* court actually meant sales only, the authority vested in the FDA by the PHSA is not so limited. In any event, plaintiffs all allege to *buy* and *sell* raw milk that is transported over state lines, so they would still run afoul of the ban if it had been limited to "sales."

Court has held already to the contrary. *See* Memorandum Opinion and Order (DR 27) at 27-28 ("'[I]nterstate commerce' has been recognized to mean nothing more than persons, products, or contraband crossing state lines . . . . In short, such conduct [as alleged by plaintiffs] plausibly involves "causing [raw milk] to be delivered into interstate commerce.") (internal citations omitted). Nevertheless, the crux of plaintiffs' argument is their assertion "interstate commerce" requires at least the sale of an article that has previously crossed state lines. *See* Pls.' Summ. J. Br. at 8; Pls.' Resist. at 17 ("[I]n this case, the raw milk is not being transported across state lines before it is sold."). According to plaintiffs, "interstate commerce" cannot include the scenario in which a person crosses state lines to purchase raw milk and then again crosses state lines with the milk. Plaintiffs' contention is plainly incorrect.

As the courts have "repeatedly made clear, Congress' power to regulate things in interstate commerce is plenary" (*United States v. Fassee*, 265 F.3d 475, 483-84 (6th Cir. 2001), *citing Gibbons v. Ogden*, 22 US (9 Wheat.) 1, 193 (1824)), and the term "commerce" is "a practical one and embraces economic activity beyond that which is traditionally considered commerce." *United States v. Bailey*, 115 F.3d 1222, 1228 n.7 (5th Cir. 1997). Indeed, the Eighth Circuit has expressly recognized the Supreme Court's repeated holdings that "crossing state lines is interstate commerce regardless of whether any commercial activity is involved." *United States v. Wright*, 128 F.3d 1274, 1275 (8th Cir. 1997) (citing, *inter alia*, *Caminetti v. United States*, 242 U.S. 470 (1917)

(transporting a person across state lines for personal purposes constitutes interstate commerce)).[9]

Plaintiffs' contention that transporting one's personal property across state lines is not interstate commerce was rejected by the Supreme Court, which held in *United States v. Hill*, the "transportation of one's own goods from state to state is interstate commerce." 248 U.S. 420, 424 (1919) (citation omitted); *see also United States v. Simpson*, 252 U.S. 465, 466-67 (1920) (fact that "liquor was intended for the personal use of the person transporting it is not material" to conclusion that it was "transported in interstate commerce"). This same logic applies to any personal article being carried across state lines, including raw milk. *See also United States v. Sinks*, 473 F.3d 1315, 1321 (10th Cir. 2007) ("Showing that an item crossed state lines is sufficient to show that it traveled in interstate commerce.").

Moreover, as FDA described in the Administrative Determination, "the concept of interstate commerce includes more than the act of carrying an article across state lines" and "'includes the *whole transaction* for which such transporting is a part . . . .'" Administrative Determination at 5 (emphasis added) (citing *Barnes v. United States*, 142 F.2d 648, 650 (9th Cir. 1944); *Bruhn's Freezer Meats of Chicago, Inc. v. U.S. Dept. of Agric.*, 438 F.2d 1332,1339 (8th Cir. 1971) ("It is settled doctrine that where one purchases goods in one state for transportation to another, the interstate commerce transaction *includes the purchase* as well as the transportation.") (emphasis added)).[10]

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[9] *See also Wright*, 128 F.3d at 1275 ("Our own cases have also consistently made clear that crossing state lines, without more, is interstate commerce.").

[10] *See also United States v. Food, 2,998 Cases . . . First Phoenix Group, Ltd.,* 64 F.3d 984, 988 (5th Cir. 1995) (It is "the entirety of a transaction [that is to be] considered when establishing whether a product is in interstate commerce, [and] a product that is

In light of the foregoing, FDA concluded in the Administrative Determination that:

> it is apparent that the sale of unpasteurized milk to a customer who intends to transport it out-of-state, either directly or through an intermediary, constitutes delivery into interstate commerce. Not only do direct shipments across state lines to consumers constitute interstate commerce, but . . . a person who purchases unpasteurized milk in one state with the intent to take it to another state (either for personal use or to distribute to others) is engaging in interstate commerce.

Administrative Determination at 5.

Plaintiffs' attempts to distinguish the cases cited by FDA in support of this conclusion are frivolous. Plaintiffs try to distinguish *Drown v. United States*, 198 F.2d 999 (9th Cir. 1952), solely on the ground that the product there had been deemed to be misbranded under the FDCA and customers were being misled into believing that the product was effective in curing disease. *See* Pls.' Summ. J. Br. at 11-12. Plaintiffs' perceived distinction has nothing to do with interstate commerce.[11] Plaintiffs' attempt to distinguish *United States* v. *Sanders,* 196 F.2d 895 (10th Cir. 1952), rests on an apparent misapprehension the case involved sales of a goods "to a broker or distributor located in another state who in turn sold the goods to the consumer." *Id.* at 10. *Sanders*, however, is nearly indistinguishable from *Drown*, for in *Sanders*, the defendant did *not* sell to out-of-state brokers, but instead sold misbranded medical devices to consumers who intended to transport them out of state. This activity constituted

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destined for sale in a state other than the place from which [it was] shipped is therefore in interstate commerce.") (internal quotations omitted); *United States v. Vidal-Cruz*, 67 F. Supp. 2d 35, 41 (D.P.R. 1999) (milk deemed to have been delivered in interstate commerce because it had been "delivered . . . to a purchaser who [the seller] knew or intended would subsequently introduce the adulterated milk into the interstate market.").

[11] It is also a distinction without a difference. Just as in *Drown* with respect to the misbranded device, FDA here has serious concerns about the safety of raw milk.

delivery into interstate commerce, and the court found it to be immaterial whether the product was transported across state lines by a common carrier, a private carrier, or by the purchasers themselves. *Sanders*, 196 F.2d at 898.[12] Plaintiffs' criticism of *Bruhn's Freezer Meats*[13] and *Simpson*[14] are similarly unhelpful, as is their citation to *U.S. v. Ruffin* (*see* Pls.' Summ. J. Br. at 8; Pls.' Resist. at 16-17). *Ruffin* has been overruled by the Supreme Court. *See Barrett v. United States*, 423 U.S. 212, 215-17 (1976). Further discussion of plaintiffs' interstate commerce argument is unnecessary.[15]

In light of the foregoing, interstate commerce plainly includes the conduct in which the plaintiffs' engage.[16]

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[12] Plaintiffs' attempt to distinguish *Barnes* v. *United States,* 142 F.2d 648, 650 (9th Cir. 1944) and *Vidal-Cruz,* 67 F. Supp. 2d at 41 on this same ground (*i.e.*, that they involved interstate shipments of products to distributors for subsequent sale) fails because, as discussed, *supra*, these elements are unnecessary to establish interstate commerce.

[13] Plaintiffs complain *Bruhn's Freezer Meats* involved a unique statutory definition of interstate commerce (*see* Pls.' Summ. J. Br. at 10), but fail to realize the language from that case cited in the Administrative Determination pertained to the definition of interstate commerce more generally under the commerce clause. *See* Administrative Determination at 9 ("It is settled doctrine that where one purchases goods in one state for transportation to another, the interstate commerce transaction includes the purchase as well as the transportation.") (quoting *Bruhn's Freezer Meats of Chicago, Inc.*, 438 F.2d at 1339).

[14] Plaintiffs criticize *Simpson* for being an old case, but it has never been overruled and continues to be cited as good authority.

[15] Although it does not pertain to the meaning of "interstate commerce," plaintiffs perceive an impermissible irrationality in FDA's decision to ban only raw milk in "final package form." *See, e.g.*, Pls. Summ. J. Br. at 8. As explained in the Final Rule, however, the PHSA Regulation focuses on raw milk in "final package form" to allow an exception for the "interstate shipment of raw milk to dairy plants *for pasteurization* or to products for which procedures are provided by regulation." 52 Fed. Reg. 29509, 29510 (emphasis added). FDA did not wish ban such commercial bulk shipments to pasteurization plants across state lines. Moreover, as plaintiffs all allege to buy and sell raw milk in "final package form," this exception could not apply to them under any circumstance.

[16] Plaintiffs' arguments to the contrary based on the recently-enacted Patient Protection and Affordable Care Act are inapplicable also. *See* Pls.' Summ. J. Br. at 12-15. In

III. Plaintiffs' Claim the Milk Standard of Identity Regulation and the PHSA Regulation Are Unconstitutional is Without Merit and Should Be Dismissed.

In both the Motion to Dismiss and Combined Brief, defendants demonstrate the Milk Standard of Identity Regulation and the PHSA Regulation do not violate the Constitution. *See* Combined Br. at 42-53; Defs.' MTD at 22-27. Defendants also explained why it was unnecessary for this Court to even entertain plaintiffs' constitutional claims because FDA has stated in the Administrative Determination it has not previously enforced either the PHSA Regulation or the Milk Standard of Identity Regulation against consumers who purchase raw milk solely for personal consumption and has no intention to alter its enforcement priorities. *See* Combined Br. 43-44; Administrative Determination at 6-9.

In their Briefs, plaintiffs do not meaningfully advance their constitutional arguments beyond those made in their Resistance to FDA's Motion to Dismiss. Therefore, beyond the two points offered below, defendants rest upon the arguments set forth in defendants' prior briefing.

First, among other consequences of this Court holding there is a fundamental right to consume demonstrably dangerous foods, would be that state and local public health laws mandating pasteurization could become constitutionally vulnerable. *See*

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those cases, several lower courts have issued various holdings on the constitutionality of the "individual mandate" element of that act, in which Congress required most Americans to purchase of health insurance. Although the constitutionality of that statute will likely be decided by the Supreme Court in the coming years, the act has absolutely nothing to do with FDA's regulation of raw milk. Contrary to plaintiffs' assertions, FDA is not regulating "inactivity" and does not *mandate* that people drink pasteurized milk (or anything else). *See* Pls.' Summ. J. Br. at 12. Instead, FDA has established minimum health and safety requirements for milk delivered in interstate commerce, just as it and many other agencies do with respect to countless other foods, as well as drugs, medical devices and other products.

Benton v. Maryland, 395 U.S. 784, 795 (1969) ("Once it is decided that a particular Bill of Rights guarantee is 'fundamental to the American scheme of justice,' . . . the same constitutional standards apply against both the State and Federal Governments.") (internal citation omitted). The Constitution, however, provides indisputably broad authority for the government (both federal and state) to protect the public health. S*ee, e.g.*, *Oregon-Wash. R. & Nav. Co. v. Washington*, 270 U.S. 87, 95 (1926) ("[T]he power of the state to take steps to prevent the introduction or spread of disease . . . (subject to the paramount authority of Congress if it decides to assume control), is beyond question."). While it may be true pasteurization was not used by the settlers in Jamestown, the notion the government can regulate milk to protect the public health is not new. *See also Adams v. City of Milwaukee*, 228 U.S. 572 (1913) (upholding municipal milk ordinance intended to protect public health); *New York v. Van De Carr*, 199 U.S. 552 (1905) (same).

Second, in claiming a constitutional right to travel protects their right to buy and sell raw milk, plaintiffs plainly attempt to circumvent state public health laws mandating pasteurization. Plaintiffs each live in a state where the sale of raw milk is illegal, or sell to people who live in such states. The constitutional right to travel does not protect a right to transport unlawful products. *See* Combined Br. at 46-47 (describing the components of the constitutional right to travel).

CONCLUSION

For the foregoing reasons and as set forth above and in defendants' Combined Brief, this Court should dismiss the plaintiffs' Amended Complaint, or, in the alternative, grant judgment in favor defendants on all counts. In the event that Count One of the

Amended Complaint is not dismissed or judgment on that count is not granted, defendants submit that the Court should reject plaintiffs' APA claims based on the merits briefing set forth above and in Section V of the Combined Brief.

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 July 1, 2011July 1, 2011.

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