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

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| 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 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 CHALLENGED REGULATIONS**

## INTRODUCTION

Before the pasteurization of milk became routine beginning in the late 1940s, scores of illnesses and deaths were caused by milk-borne illnesses. *See infra* at 31 (*citing* FDA3-001532-1674 (epidemiological statistics for milk-borne disease outbreaks occurring between 1923 and 1949); *see also* note 19, *infra*.). Today, because of the pasteurization of milk and milk products, the occurrence of milk-borne disease have become relatively rare. Plaintiffs wish to turn back the clock and undo the federal regulations that prohibit the introduction of potentially dangerous unpasteurized milk into interstate commerce.

As shown below, all of plaintiffs' claims are facial challenges to regulations that were issued in final form more than twenty years ago. Thus, summary judgment should be granted to defendants on all claims because the claims are barred by the statute of limitations, 28 U.S.C. § 2401(a).

In addition, plaintiffs' claims under the Administrative Procedure Act are baseless. Count One alleges that the challenged regulations are *ultra vires* and arbitrary and capricious, but the regulations fall squarely within the broad authority vested in the Food and Drug Administration ("FDA") to issue regulations to prevent the spread of communicable diseases, and they are supported by an administrative record replete with scientific evidence that unpasteurized milk may contain dangerous bacteria. Accordingly, this Court should reject plaintiffs' challenge to FDA's milk regulations.

Moreover, as set forth below and in defendants' Motion to Dismiss (DR[1] 11) ("MTD"), should this Court conclude that plaintiffs' constitutional claims are not barred by the statute of limitations, they should be rejected nonetheless because they fail to state a claim upon which relief can be granted. Counts Two, Three, and Five, alleging that the challenged regulations infringe upon plaintiffs' constitutional right to travel and violate their constitutionally guaranteed right to privacy and substantive due process rights, respectively, are meritless. Each count asks this Court to dramatically expand the scope of existing jurisprudence under the Fifth Amendment by recognizing rights not previously recognized by a single court. Finally, Count Four's contention that the regulations run afoul of the non-delegation doctrine should be rejected because the statutory provisions authorizing the issuance of the challenged regulations provide sufficiently intelligible standards for FDA. Accordingly, defendants' Motion to Dismiss should be granted with respect to all of plaintiffs' claims.

## PROCEDURAL HISTORY

In a Motion to Dismiss filed in April 2010, defendants argued that plaintiffs do not have standing and that their claims are not ripe because FDA has taken no enforcement action against any of them. *See* MTD 9-17 (DR 11). Defendants also argued that plaintiffs had failed to state a claim under which relief could be granted because they had failed to exhaust their administrative remedies, the challenged regulations do not violate the non-delegation doctrine or exceed FDA's statutory authority, and the challenged regulations do not infringe upon the constitutional right to travel or

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

substantive due process rights. *See id*. at 17-29. In a Memorandum and Opinion Order Regarding Defendants' Motion to Dismiss, (DR 27) (the "Opinion"), the Court denied without prejudice defendants' challenges to subject matter jurisdiction, denied defendants' administrative exhaustion claims, and reserved ruling on whether plaintiffs' Amended Complaint failed to state a claim upon which relief can be granted. *See* Opinion at 25. The Court then stayed further proceedings to provide plaintiffs with the opportunity to file a Citizen Petition raising three specific questions with the FDA. *See* Opinion at 52-53, 55. Plaintiffs subsequently declined the opportunity provided by the Court to file a Citizen Petition. The parties agreed instead that FDA would accept the referral of the questions posed by the Court in accordance with the doctrine of primary jurisdiction and the procedures contemplated by 21 C.F.R. §§ 10.25(c) and 10.60. On September 17, 2010, the parties jointly proposed this plan to the Court, which the Court accepted and reduced to an order dated that same day. *See* DR 28. As discussed in Section III, *infra*, FDA issued its response to the Court's questions in the form of an administrative determination dated March 16, 2011, ("Administrative Determination"), a copy of which was filed with the Court. *See* Attachment A to Defendants' Status Report of March 16, 2011, (DR 43).

After the Administrative Determination issued, defendants proposed that the parties file supplemental briefs on defendants' Motion to Dismiss and stated their intention to move, in the alternative, for judgment regarding the merits of plaintiffs' pre-enforcement challenges under the APA and to present any affirmative defenses. *See* Defs.' Status Report of March 16, 2011, (DR 43). The Court concurred with this

proposed approach in its Order Lifting Stay and Setting Supplemental Briefing Schedule dated April 1, 2011, (DR 45).

Defendants hereby file this 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 Challenged Regulations in accordance with the Court's order dated April 1, 2011. Following a brief background section describing further the challenged regulations and the Administrative Determination, defendants explain in Section IV, *infra*, why judgment on all of plaintiffs' claims should be granted in favor of defendants because they are barred by the statute of limitations. In Section V, *infra*, defendants demonstrate that 21 C.F.R. § 1240.61(a) is neither *ultra vires* nor arbitrary and capricious, and show why plaintiffs' challenge to 21 C.F.R. § 131.110, a regulation never previously enforced against *anyone*, is not justiciable. Section VI contains defendants' supplemental briefing on their renewed motion to dismiss plaintiffs' constitutional claims.

## BACKGROUND

### I. The PHSA and the Ban on Interstate Distribution of Unpasteurized Milk, 21 C.F.R. § 1240.61.

As discussed in defendants' Motion to Dismiss, *see* MTD 5-7, FDA is authorized under the PHSA, 42 U.S.C. § 264(a), to make and enforce regulations that, in the agency's judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases from one state to another. Congress used broad statutory language in the PHSA and placed no limitation on the types 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.").

Pursuant to its authority under of the PHSA, FDA promulgated a ban on the interstate sale of unpasteurized milk:

> 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 . . . .

21 C.F.R. § 1240.61(a) (the "PHSA Regulation");[2] *see also* Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce. 52 Fed. Reg. 29509 (Aug. 10, 1987); *Public Citizen v. Heckler*, 602 F. Supp. 611, 613 (D.D.C. 1985). However, because the ban is applicable only to unpasteurized milk that is delivered into interstate commerce, individual states presently control whether unpasteurized milk is available to their residents locally through intrastate sales.[3]

As discussed further in Section V, *infra*, FDA promulgated the PHSA Regulation in 1987, after spending thirteen years collecting and evaluating scientific information regarding the health risks associated with unpasteurized milk, holding a public hearing

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[2] "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."

[3] *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").

that resulted in over 300 comments, and ultimately concluding that consumption of these products was linked to the outbreak of disease.

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

As also discussed in defendants' Motion to Dismiss, in enacting the Federal Food, Drug and Cosmetic Act ("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)(A). 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.").

Acting under 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."

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

21 C.F.R. § 131.110(a) (the "Milk Standard of Identity Regulation," which, together with the PHSA Regulation, are referred to herein as the "Regulations"). The 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 under the FDCA. *See* 21 U.S.C. § 343(g). Because the standard of identity regulation applies only to foods in interstate commerce, the requirement of the Milk Standard of Identity Regulation that "milk" be pasteurized "does not conflict with the right of individual states to authorize the *intra*state distribution of raw milk to consumers." *See* Final Rule, 38 Fed. Reg. 27924 (Oct. 10, 1973) (emphasis added).

**III. The FDA's Administrative Determination.**

In its Administrative Determination, FDA responded to three questions that had been referred by the Court and accepted by FDA pursuant to Court's Order dated September 17, 2010.[5] The Administrative Determination reviewed the case law on

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[5] As set forth in the Court's Order (*see* pp. 2-3) the questions referred were: "Whether 21 C.F.R. § 1240.61 applies to and proscribes the conduct of the following persons:

(A) 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

(B) 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, where the principal then consumes the raw milk or gives it to the principal's friends or family members; or

(continued...)

"interstate commerce" (the meaning of which term is relevant to the construction of the Regulations) and noted that "[a]n article is in interstate commerce if it is transported across state lines, but the concept of interstate commerce includes more than the act of carrying an article across state lines. Interstate commerce 'includes the whole transaction for which such transporting is a part . . . .'" Admin. Determination 5 (*quoting Barnes v. United States*, 142 F.2d 648, 650 (9th Cir. 1944); *Bruhn's Freezer Meats of Chicago, Inc. v. USDA*, 438 F.3d 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."). FDA concluded that "a person who has directly shipped unpasteurized milk to another state has likely 'cause[d] to be delivered' the milk into interstate commerce in violation of the PHSA Regulation." Admin. Determination 5-6. "This same conclusion holds with respect to a person who purchases raw milk with the intent to carry it out of state for distribution to others or for his own personal consumption." *Id.* at 6.

FDA went on to explain, however, that "[d]espite this clear and broad regulatory authority over the introduction of raw milk into interstate commerce, the Agency has consistently exercised its enforcement discretion with respect to consumers." *Id.* "In so doing, *FDA has <u>never</u> sought to bring an enforcement action against an individual who purchased and transported raw milk across state lines solely for his or her personal consumption*. Among other reasons, it would not constitute an efficient use of Agency

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[5](...continued)
(C) a producer of raw milk who sells raw milk in a state where it is legal to do so in an intrastate transaction to persons that he knows are from out of state?"

resources to focus on end-users and consumers. This is true not only with respect to raw milk, but generally also with other products regulated by FDA." *Id.* (emphasis added). With respect to the hypothetical agent purchasing raw milk for delivery to persons in other states and a hypothetical producer knowingly selling raw milk to out-of-state customers, FDA concluded that the PHSA Regulation would proscribe the conduct, but whether FDA would consider an enforcement action would depend on the particular factual circumstances. *See id.* at 8-9. As the Agency ultimately concluded in response to the Court's questions:

> FDA will seek to enforce the law as it becomes aware of potential violations of the PHSA and 21 C.F.R. § 1240.61. FDA, however, intends to continue to direct its limited resources to enforcement actions against those who produce and/or distribute raw, unpasteurized milk in interstate commerce. FDA has not brought enforcement actions against individual consumers in the past and, subject to the considerations described above, has no present intent to do so in the future. Similarly, if a producer solicits interstate sales and/or regularly sells raw milk that is ultimately transported across state lines, FDA would review the facts for possible regulatory action.

*Id.* at 9.

## ARGUMENT

### IV. Plaintiffs' Claims Are Time-Barred.

Plaintiffs challenge two regulations that were issued in final in 1973 and 1987, alleging that those regulations are arbitrary and capricious, in excess of FDA's statutory authority, and unconstitutional. These challenges are presented not in the context of an actual application of the Regulations to any of the plaintiffs, but instead as a pre-enforcement facial attack on their validity. Because any cause of action attacking these

regulations on their face accrued at the time of final agency action – *i.e.*, when the Regulations were promulgated – plaintiffs' claims are all time-barred by the six-year statute of limitations set forth in 28 U.S.C. § 2401(a). Summary judgment should therefore be entered in favor of defendants.[6]

### A. The Statute of Limitations in 28 U.S.C. § 2401(a) Bars Untimely Facial Attacks.

Plaintiffs brought this declaratory judgment action under the United States Constitution and the APA. App. 3, ¶ 1. The general statute of limitations set forth in 28 U.S.C. § 2401(a) applies to such claims. *See Izaak Walton League of Am., Inc., v. Kimbell,* 558 F.3d 751, 758 (8th Cir. 2009) (*citing Sierra Club v. U.S. Army Corps of Eng'rs, et al.*, 446 F.3d 808, 813 (8th Cir. 2006)); *Alaska Legislative Council v. Babbitt*, 15 F. Supp. 2d 19, 23 (D.D.C. 1998) (applying § 2401(a) to bar facial Fifth Amendment challenge to statute); *Carter v. Dept. of Navy*, 2006 U.S. Dist. LEXIS 59767 *20 (D.D.C. Aug. 24, 2006) (applying § 2401(a) to bar alleged constitutional and statutory

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[6] Motions for summary judgment essentially "define disputed facts and issues and . . . dispose of unmeritorious claims." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 584 (2007); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). Summary judgment is appropriate if viewing the record in the light most favorable to the non-moving party, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005). The moving party bears "the initial responsibility of informing the district court of the basis for its motion and identifying those portions of the record, which show a lack of a genuine issue." *Hartnagel v. Norman*, 953 F.2d 394, 395 (*citing Celotex*, 477 U.S. at 323). The opposing party may not "rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial." *Mosley v. City of Northwoods*, 415 F.3d 908, 910 (8th Cir. 2005) (*quoting Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995)). If a party fails to make a sufficient showing of an essential element of a claim or defense with respect to which that party has the burden of proof, then the opposing party is "entitled to judgment as a matter of law." *Celotex*, 477 U.S. at 322.

violations). Section 2401(a) of Title 28, United States Code, provides that "[e]xcept as provided by the Contract Disputes Act of 1978, every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues." This statute of limitation applies to all of plaintiffs' claims, including their constitutional claims. *See Daniels v. United States*, 532 U.S. 374, 381 (2001) ("Procedural barriers, such as statutes of limitations and rules concerning procedural default and exhaustion of remedies, operate to limit access to review on the merits of a constitutional claim."); *see also Kendall v. Army Bd. of Corr. of Military Records*, 996 F.2d 362, 365 (D.C. Cir.1993) (holding that § 2401(a) "applies to *all* civil actions whether legal, equitable, or mixed") (emphasis added).

A "claim against [the] United States first accrues 'on the date when all the events have occurred which fix the liability of the Government and entitle the claimant to institute an action.'" *Izaak Walton*, 558 F.3d at 759 (*citing Chandler v. U.S. Air Force*, 255 F.3d 919, 921 (8th Cir. 2001)). Where an agency has issued "a definitive statement of its position, determining the rights and obligations of the parties," such as the issuance of the Regulations, that action is final for purposes of judicial review. *See Sierra Club*, 446 F.3d at 813 (*citing Bell v. New Jersey*, 461 U.S. 773, 779-80 (1983)).

Facial challenges to the validity of a regulation must be brought within six years after the regulation's publication in the Federal Register. *Wind River Mining Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991); *Dunn-McCampbell Royalty Interest, Inc., v. Nat'l Park Svc.*, 112 F.3d 1283, 1287 (5th Cir. 1997), *rev'd on other grounds*, 630 F.3d 431 (5th Cir. 2011); *Impro Prods., Inc. v. Block*, 722 F.2d 845, 849-51 (D.C. Cir. 1983) (noting that the court had "been directed toward no activity that occurred

during the six years prior to filing that amounts to final agency action"); *see also Izaak Walton*, 558 F.3d at 761 (environmental group's claims that the Forest Service violated a statute accrued when the Forest Service published maps and legal description in the Federal Register, as the "appearance of regulations in the Federal Register g[ives] legal notice of their content to all affected thereby") (*quoting United States v. Wiley's Cove Ranch*, 295 F.2d 436, 447 (8th Cir. 1961)); *P&V Enters. v. United States Corps of Engr's*, 466 F. Supp. 2d 134, 150 (D.D.C. 2006) (holding as time-barred plaintiffs' claims for injunctive and declaratory relief from a rule promulgated nineteen years prior to the action that plaintiffs contended exceeded the Corps' statutory); *Shiny Rock Mining Corp. v. United States*, 906 F.2d 1362, 1364 (9th Cir. 1990) (claim against United States time-barred because publication in the Federal Register "is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance"); *cf. Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384-85 (1947) ("Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the Federal Register gives legal notice of their contents."); *United States v. Wiley's Cove Ranch*, 295 F.2d 436, 446 (8th Cir. 1961) (noting "he who deals with the government is bound by duly promulgated regulations published in the Federal Register whether he has actual knowledge of them or not").

### B. Plaintiffs' Claims Are Time-Barred Because They Attack the Facial Validity of the Regulations.

The nature of plaintiffs' challenges to the Regulations and the statements in their Amended Complaint and briefs establish beyond cavil that they are challenging the facial validity of the Regulations, not FDA's application to them in a specific context. Indeed, plaintiffs concede that the promulgation of both the PHSA Regulation and the Milk Standard of Identity Regulation constitutes the final agency action at issue, and plaintiffs describe those regulations as the source of their alleged injury. *See* App. 22 ("Plaintiffs' allegations are based on final regulations adopted by FDA, which is clear 'final agency action' for purposes of the APA, causing actual existing injury to the Plaintiffs . . . ."); *see also* App. 20 ("[p]laintiffs do not need to 'wait' for FDA to 'enforce' the law for this Court to declare whether 1240.61 and 131.110 are unconstitutional as applied to Plaintiffs' conduct").

Plaintiffs likewise seek to invalidate the Regulations in all of their applications. In Count One, plaintiffs allege that the Regulations "exceed FDA's statutory authority and are arbitrary and capricious," "for which declaratory and other injunctive relief is available and should issue under 5 U.S.C. 702 and 706." App. 12, 14. To argue that an agency acted arbitrarily and capriciously, exceeded its statutory authority, and promulgated regulations inconsistent with enabling statutes is to say every potential application of the regulations is invalid and the regulations are therefore facially invalid. *See Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687, 699-700 (1995) (construing challenge as facial when it would have invalidated the Secretary's understanding of 'harm' in every circumstance).

Perhaps most importantly, with the exception of Plaintiff Eric Wagoner discussed in Section IV.C, *infra*, none of the plaintiffs even allege that FDA has applied or sought to apply the challenged Regulations to them in particular. Instead, in an effort to satisfy their obligation to plead a justiciable controversy under Article III of the Constitution, plaintiffs repeatedly and consistently allege that their "injury" is having to choose between abandoning their rights and "*risking enforcement actions.*" App. 22 (emphasis added); App. 19-21 (same); *see also* App. 11, ¶ 59 ("A declaratory judgment action is the appropriate action to bring when faced with a Hobson's choice, *i.e.*, either comply with a law that is believed to be illegal, or ignore the illegal law and face the *possible* consequences of noncompliance.") (emphasis added). As such, all of these plaintiffs are unquestionably mounting a facial challenge to the regulations.[7] Plaintiffs' facial challenges to the Regulations, which are based upon the text of the Regulations, the APA, the enabling statutes, the Constitution, and case law, and little, if nothing, else, *see* App. 12-14, ¶¶ 68-99, accrued the day the Regulations were published in the Federal Register in 1973 and 1987. *See also* 38 Fed. Reg. 27924 (Oct. 10, 1973) (promulgating 21 C.F.R. § 131.110); 52 Fed. Reg. 29509 (Aug. 10, 1987) (promulgating 21 C.F.R. § 1240.61). Therefore, the statute of limitations for those claims ran in 1979 and 1993, six years, respectively, after promulgation of the Milk Standard of Identity Regulation in 1973 and the PHSA Regulation in 1987.

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[7] Tellingly, when defendants challenged plaintiffs' standing to maintain this action, plaintiffs resorted to proffering evidence of FDA agency action against *non*-parties because FDA has taken no such action against plaintiffs. App. 19-21. (citing affidavits by attorneys from the Farm-to-Consumer Legal Defense Fund describing FDA enforcement action against non-parties). The experiences of non-parties do not, and cannot, constitute final agency action with respect to the plaintiffs here.

### C. Plaintiffs Cannot Avoid the Statute of Limitations by Characterizing Their Claims as "As-Applied" Challenges to the Regulations Because None of the Plaintiffs Have Demonstrated "Final Agency Action" Against Them by FDA in the Preceding Six Years.

Because their facial challenges to the Regulations are time-barred, it appears plaintiffs have attempted to characterize their claims as "as-applied." After the six-year statute of limitations has run on a facial challenge, as it has here, a challenge to the validity of an agency's rule may proceed only through an as-applied challenge requesting judicial review of the agency's adverse application of the rule to the particular challenger.[8] *Wind River*, 946 F.2d at 715; *see also Tripoli Rocketry Assoc. v. United States BATF*, 2002 U.S. Dist. LEXIS 27588, *14-*16 (D.D.C. 2002) (§ 2401(a) "does not foreclose subsequent examination of a rule where properly brought before . . . [a] court for review of further [agency] action applying it.") (*citing Nat'l Labor Relations Bd. Union v. Fed. Labor Relations Auth.*, 834 F.2d 191, 195-96 (D.C. Cir. 1987) (citations omitted)); *P&V Enters.*, 466 F. Supp. 2d at 142; *Oksner v. Blakey*, 2007 U.S. Dist. LEXIS 83697, *18 (N.D. Cal. 2007). But "to sustain such a challenge . . . the [plaintiff] must show some direct, final agency action involving the . . . plaintiff [that occurred] within the [new limitation period]." *See Dunn-McCampbell*, 112 F.3d at 1287. Plaintiffs cannot make this showing.

Consumer plaintiffs Donnelly, Allen, Miller, Heckman, and Rose cannot show there has been final agency action applied to them within the limitations period because

[8] A second exception to the statute of limitations—not applicable here—is available to a party who petitions the agency for amendment or rescission of the rule and then appeals the agency's decision. *See Wind River*, 946 F.2d at 715; *P&V Enters.*, 466 F. Supp. 2d at 142. Plaintiffs have not petitioned FDA to amend or rescind the regulations.

they do not even *allege* that FDA has *ever* taken any agency action against them beyond promulgating the regulations at issue. Instead, in an attempt to meet their burden of establishing the existence of a justiciable controversy, these plaintiffs merely allege that they *engage in conduct* they believe is prohibited by the Regulations and that they feel they must choose between engaging in such conduct or risking the threat of enforcement action.[9] *See, e.g.*, App. 4-5, ¶¶ 8-9 (Plaintiff Donnelly alleges that she "drove from Iowa into Nebraska and legally purchased and obtained raw milk[,] traveled back into Iowa in possession of the raw milk where she and her family then consumed the milk" and such activity "continues to this day"); App. 11, ¶ 58; *see also* App. 5-7, ¶¶ 10-25 (describing similar allegations regarding plaintiffs Allen, Miller, Heckman, and Rose). Plaintiffs' "Hobson's choices," if they exist at all,[10] came long after the running of the statute of limitations.

Indeed, the one raw milk producer plaintiff in this case, Plaintiff Buck, admits the *absence* of FDA interference with his activities. Specifically, he alleges that he has held a retail raw milk license since 2006, has personal knowledge that out of state customers purchase raw milk at his farm and at the retail store where his milk is sold, but "[he] has *never had any sanctions or penalties levied against his dairy*; [and] he has *never had to dump even a single load of milk* since he has been in business." App. 9-10, ¶¶ 37-43 (emphasis added). Thus, like the consumer plaintiffs, he cannot make the necessary showing for a timely "as-applied" challenge.

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[9] Plaintiffs can point to no cases holding that the fear of enforcement can constitute a final agency action for purposes of the statute of limitations.

[10] Even plaintiff Donnelly's alleged fear is specious because she continues to engage in the conduct that she claims causes her anxiety.

Unlike the other plaintiffs, Plaintiff Wagoner apparently contends that *FDA* applied the Regulations to him (including milk he was transporting for Plaintiff Cooper) within the preceding six years; however, this claim rests on a conclusory allegation that is unsupported by the facts. *See Allen v. Entergy Corp.*, 181 F.3d 902, 906 (8th Cir. 1999) (conclusory affidavits devoid of specific factual allegations rebutting the moving party's evidence cannot defeat a summary judgment motion).

The Amended Complaint alleges that it is illegal to sell raw milk for human consumption in the State of Georgia and that plaintiff Wagoner owns a business, Athens Locally Grown ("ALG"), that purchases raw milk in South Carolina and transports the milk to ALG members, some of whom are located in Georgia. App. 7-9, ¶¶ 27, 32, 33. Plaintiff Wagoner states that on "October 15, 2009, an ALG volunteer was driving [plaintiff Wagoner's] delivery truck from South Carolina into Georgia with about 110 gallons of raw milk . . . ." App. 25, ¶¶ 6-7; *see also* App. 8-9, ¶ 33. Plaintiff Wagoner further declares that "[u]pon reaching Georgia, [the] truck was searched and seized *by officials from Georgia* without a warrant. *Officials from Georgia embargoed* the raw milk in my truck without a search warrant." App. 25, ¶ 8 (emphasis added); *see also* App. 8-9 ¶ 33. He then declares that on October 19, 2009, "110 gallons of raw milk . . . were destroyed at the order of the Georgia officials *and of the FDA* without a warrant or other legal process." App. 25, ¶ 10 (emphasis added); App. 9, ¶ 34.

As set forth in declarations submitted by Marybeth Willis from FDA and Peggy Gates from the Georgia Department of Agriculture, in reality, officials from Georgia did not discover the milk in question until ALG had *set up a booth at farmer's market* to distribute the milk on or about October 15, 2009. *See* App. 32, ¶¶ 2-3. At that time,

Georgia officials, App. 32-33, ¶¶ 4-8, without any involvement by FDA, App. 29, ¶¶ 9-10, embargoed the raw milk *at the farmer's market*. App. 32, ¶ 4. Wagoner was given a Stop Sale notice and tags were placed on each cooler. App. 32, ¶ 6. Georgia officials advised Wagoner the milk needed to be stored under embargo until the following Monday or be voluntarily destroyed. App. 32, ¶ 5. Mr. Wagoner agreed to voluntarily destroy the milk, but because a place to destroy the milk could not be found, Mr. Wagoner asked - and received - permission from Georgia officials to transport the milk to his home for destruction. App. 32, ¶ 5.

The only FDA official present at the destruction of the milk, Marybeth Willis, *see* App. 25, ¶ 11, avers that she never ordered or otherwise directed Mr. Wagoner or anyone else to destroy the milk. App. 29, ¶¶ 9-10. FDA did not initiate an enforcement action against plaintiff Wagoner's milk and instead merely accompanied the Georgia state officials who witnessed his voluntary destruction of the milk. App. 29, ¶¶ 6, 9-10. Plaintiff Wagoner notes that the incident was videotaped and posted on YouTube, App. 26, ¶¶ 12-13, but that video does not support his contention that Ms. Willis ordered the destruction of the milk.

Furthermore, the FDA representative who witnessed the destruction of the milk had *no authority* to seize the milk or order its destruction. App. 29, ¶ 10. As explained in the Declaration of Marybeth Willis, if FDA were to have taken an action to seize and destroy the embargoed milk, this would have involved a multi-step process beginning with a recommendation from FDA's Atlanta District Office to FDA's Center for Food Safety and Nutrition ("CFSAN") in College Park, Maryland. *Id.* Only upon the concurrence of CFSAN, and the subsequent concurrence of FDA's Office of Chief

Counsel, would the matter be referred to the Department of Justice. *Id.*; *cf. Heckler v. Chaney*, 470 U.S. 821, 835 (1985) ("the [FDCA] charges the Secretary only with *recommending* prosecution") (emphasis added). Only the Department of Justice has the authority to initiate a judicial proceeding that could result in a seizure, and no such proceeding was ever initiated with respect to the embargoed raw milk in Mr. Wagoner's possession. App. 29, ¶ 10.

In short, Plaintiff Wagoner's contention that *FDA* ordered destruction of the milk rests on nothing other than the bald and conclusory assertion that after *Georgia* officials searched his truck and *Georgia* officials embargoed the milk the milk was destroyed at the order of the Georgia officials and the FDA. The mere presence of an FDA representative observing a party voluntarily destroying a food product under state embargo does not convert a state condemnation proceeding into a federally-authorized *in rem* seizure.[11]

### D. Plaintiffs' Arbitrary and Capricious Claims Are Time-Barred in Any Event.

Even if this Court were to conclude that the events in Georgia enable plaintiff Wagoner to mount a timely "as-applied" challenge that the Regulations are *ultra vires* or unconstitutional, his policy-based arbitrary and capricious attack remains time-barred.

[11] To the extent plaintiff Cooper claimed injury due to the same events as Wagoner, the above facts demonstrate that Cooper could not have been subjected to any final agency action by FDA.

As the Ninth Circuit has explained:

> If a person wishes to . . . bring a *policy-based facial challenge* to the government's decision, that . . . must be brought within six years of the decision. . . . The grounds for such challenges will usually be apparent to any interested citizen within a six-year period following promulgation of the decision; one does not need to have a preexisting mining claim in an affected territory in order to assess the wisdom of a governmental policy decision or to discover procedural errors in the adoption of a policy. The government's interest in finality outweighs a late-comer's desire to protest the agency's action as a matter of policy or procedure. [¶] If, however, a challenger contests the substance of an agency decision *as exceeding constitutional or statutory authority*, the challenger may do so later than six years following the decision by filing a complaint for review of the adverse application of the decision to the particular challenger.

*Wind River*, 946 F.2d at 715 (emphasis added).

The allegations in Count One of the Amended Complaint make clear that plaintiffs seek to raise some objections to the Regulations that are the very types of policy-based facial challenges that were barred by § 2401(a) six years after the publication of the Regulations. For example, plaintiffs claim that FDA "could use a less stringent means of regulating raw milk" by, for example, use of warning labels, App. 11, ¶¶ 79-81. Such claims must be rejected. *See Wind River*, 946 F.2d at 715; *see, e.g.*, *Massachusetts Mfg. Extension Partnership v. Locke*, ---- F. Supp. 2d ----, 2010 WL 2679835 *8 (D.D.C.) (July 7, 2010) (holding a claim that an "in-kind contribution cap" regulation was arbitrary and capricious because NIST "never provided an explanation for the cost cap" was barred six years after the final rule was published).

## V. FDA's Issuance of the Regulations Was Neither *Ultra Vires* Nor Arbitrary and Capricious.[12]

### A. Review under the APA.

The APA provides a limited waiver of sovereign immunity, *Branstad v. Glickman*, 118 F. Supp. 2d 925, 934-35 (N.D. Iowa 2000), and entitles "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . to judicial review thereof." 5 U.S.C. § 702. Under the APA, an agency decision shall not be set aside unless the court finds that the agency's conclusions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id*. § 706; *Falk v. United States*, 452 F.3d 951, 953 (8th Cir. 2006). Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. *Id.*

The court is not empowered to substitute its judgment for that of the agency. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983); *see also South Dakota v. United States*, 423 F.3d 790, 799 (8th Cir. 2005) ("we do not substitute our judgment for that of the agency"). Rather, the court must determine whether the agency's "decision was based on a consideration of the relevant factors and . . . there has been [no] clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational

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[12] Defendants' Brief on the Merits in Support of FDA's Promulgation of Challenged Regulations is presented here in the alternative to their Motion for Summary Judgment and Memorandum in support thereof. *See* LR 56(i) ( "Ordinarily, motions for summary judgment are not appropriate in actions for judicial review based on an administrative record . . . .").

connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (*quoting Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *see also Falk*, 452 F.3d at 953 ("Administrative action may be regarded as arbitrary and capricious only where it is not supportable on any rational basis."). A sufficiently rational administrative decision should stand "even if the evidence would have also supported the opposite conclusion." *South Dakota*, 423 F.3d at 799.

"It 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." *Voyageurs Nat. Park Assoc. v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004) (*citing Overton Park,* 401 U.S. at 420); *see also Newton Cnty. Wildlife Assoc. v. Rogers,* 141 F.3d 803, 807 (8th Cir. 1998). It is the administrative record compiled by the agency, "'not some new record made initially in the reviewing court,' [that] becomes the 'focal point' for judicial review." *Id.* (*quoting Camp v. Pitts*, 411 U.S. 138, 142 (1973)).[13] As explained by the Eighth Circuit, "[b]y 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." *Id.*

Where, as here, a court is reviewing the decision of an administrative agency, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did."

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[13] Plaintiffs have submitted to this court various materials in connection with their status reports. *See, e.g.*, Pls.' Status Report for March 2011 (DR 44, Ex. A) (attaching CENTERS FOR DISEASE CONTROL AND PREVENTION, POPULATION SURVEY ATLAS OF EXPOSURES (2006-2007)). None of these materials are a part of the administrative record in this case and thus they are not relevant to the Court's decision.

*See Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985); *see also Thomas v. EPA*, 2007 WL 2127881, at *1 (N.D. Iowa July 23, 2007) (observing that the normal Rule 56 standard does not apply in APA cases); *Willingham v. Dep't of Labor*, 475 F. Supp. 2d 607, 611 (N.D. Tex. 2007) (reviewing an administrative decision "calls for a modified standard: whether the agency acted appropriately given the standards of review set forth by the [APA] or the statute authorizing the agency's action."); *Environment Now! v. Espy*, 877 F. Supp. 1397, 1421 (E.D. Cal. 1994) ("The question is not whether there is a genuine issue of material fact, but rather whether the agency action was arbitrary, capricious, an abuse of discretion, not in accordance with law, or not supported by substantial evidence on the record taken as a whole.") (citation omitted).

### B. FDA's Legal Interpretations and Scientific Judgments Are Entitled to Deference.

This action challenges FDA's interpretation of statutory provisions that FDA is charged with implementing, regulations that the agency issued through notice and comment rulemaking, and the agency's evaluation of scientific data within its area of expertise. Well-established precedent dictates that this Court give deference to FDA in each of these contexts.

The Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), and its progeny set forth a two-step framework for reviewing an administrative agency's interpretation of its statute. Under *Chevron* step 1: "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the

court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. *Chevron* step 2 applies when Congress has not directly addressed the issue or has done so ambiguously. In that event, the Court may not "simply impose its own construction on the statute," but rather must determine whether the agency's construction is based on a permissible interpretation of the statute. *See id.* at 843; *id.* at 843-44 & n.11 (in case of ambiguity, court must uphold agency's interpretation if construction is permissible under the statute; a court need not conclude that agency construction was the only one it permissibly could have adopted or even the reading the court would have reached); *see also Barnhart v. Walton*, 535 U.S. 212, 218 (2002) (reviewing court must decide: (1) whether the statute unambiguously forbids agency interpretation, and (2) whether the agency interpretation exceeds the bounds of the permissible).

Moreover, when a court is evaluating an agency's interpretation of its own regulations, the agency is entitled to "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *see also Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 390 (2008) (courts accept an agency's interpretation of its regulations unless the agency's position is "plainly erroneous or inconsistent with the regulation") (internal quotations omitted) (*citing Auer v. Robbins*, 519 U.S. 452, 461 (1997)); *Clark v. Dept. of Ag.*, 537 F.3d 934, 940 (8th Cir. 2008) ("We have interpreted this deference as amounting to 'controlling weight unless [the regulation is] 'arbitrary, capricious, or manifestly contrary to the statute.'") (*quoting Friends of Boundary Waters Wilderness v. Bosworth,* 437 F.3d 815, 822 (8th Cir. 2006)).

Finally, when, as here, an agency's decision is based on evaluation of scientific information within the agency's area of scientific or technical expertise, its decisions are traditionally accorded great deference. *Downer v. Dep't of Ag.*, 97 F.3d 999, 1002 (8th Cir. 1996) ("An agency making fact-based determinations in its own field of expertise, *particularly where those determinations are wrapped up with scientific judgments*, must be permitted 'to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.'") (*quoting Marsh v. Oregon Nat. Res. Council*, 490 U.S. 360, 377-78 (1996) (emphasis added)); *see also Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1000 (D.C. Cir. 2008). Courts "review scientific judgments of the agency 'not as the chemist, biologist, or statistician that [they] are qualified neither by training nor experience to be, but as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality.'" *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997) (*quoting Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976)).

### C. FDA's Promulgation of the PHSA Regulation Was Not *Ultra Vires*.

FDA issued the PHSA Regulation acting under the broad grant of authority conferred by section 361(a) of the PHSA, which states:

> The Surgeon General, with the approval of the Secretary, ***is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases*** from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as

> to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

42 U.S.C. § 264(a) (emphasis added). This broad authority has been delegated to FDA.[14] Because section 361 of the PHSA is remedial legislation aimed at protecting the public health, it is entitled to liberal construction. *See, e.g.*, *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (remedial legislation is to be afforded liberal construction); *Hull Co. v. Hauser's Foods, Inc.*, 924 F.2d 777, 782 (8th Cir. 1991) ("remedial legislation should be given a liberal construction to effectuate its statutory purpose"); *Int'l Nutrition v. United States Dep't of Health & Human Svcs.,* 676 F.2d 338, 341 (8th Cir. 1982) (same).

FDA's promulgation of the PHSA Regulation, through notice and comment rulemaking following the *Public Citizen II* decision, falls squarely within the authority that Congress vested in the agency. *See also 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). The illnesses caused by bacteria in unpasteurized milk, such as *Salmonella*, *Listeria*, and *Campylobacter*, are, without question, communicable diseases. *See* 21 C.F.R. § 1240.3 (defining communicable diseases in relevant part as

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[14] In 1944, Congress passed the PHSA, which vested certain authority in the Surgeon General. Pub. L. No. 111-25, 58 Stat. 703, 42 U.S.C. § 264(a) (emphasis added). The Office of Surgeon General was abolished by section 3 of 1966 Reorg. Plan No. 3, eff. June 25, 1966, 31 Fed. Reg. 8855, 80 Stat. 1610, and all of its functions were transferred to the Secretary of Health, Education, and Welfare (now Secretary of Health and Human Services ("HHS")) by section 1 of 1966 Reorg. Plan No. 3, set out under 42 U.S.C. § 202. The HHS Secretary's authority has been delegated to FDA. *See* FDA Staff Manual Guide 1410.10.1.A.3 (*available at* http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm).

"[i]llnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host . . . through the agency of an intermediate . . . vector, or the inanimate environment."). FDA acted to decrease the threat of milk-borne pathogens when the evidence was overwhelming that raw milk presented a public health threat. *See Public Citizen II*, 653 F. Supp. at 1238 ("[O]verwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified, has been presented."). Moreover, as discussed below, the voluminous administrative record provided compelling and irrefutable support for the PHSA Regulation. There is, in short, no basis for claiming that the FDA's promulgation of the PHSA Regulation exceeded FDA's authority. Indeed, such an argument was effectively foreclosed by the *Public Citizen II* court's decision. *Id.*

### D. FDA's Promulgation of the PHSA Regulation Was Neither Arbitrary Nor Capricious.

#### 1. The Administrative Record Contains Ample Evidence Documenting the Dangers of Raw Milk.

In response to its August 3, 1984, notice of public hearing requesting information on whether milk and milk products sold for human consumption should be pasteurized (*see* Notice of Public Hearing To Receive Information on Whether Milk and Milk Products Sold for Human Consumption Should Be Pasteurized, 49 Fed. Reg. 31065 (August 3, 1984)), FDA received extensive information about the health risks of raw milk. Numerous state public health authorities formally lodged their view that raw milk should be banned from interstate commerce, or even banned altogether. For instance, as described by the Michigan Department of Agriculture:

> [t]he consumption of raw milk including certified raw milk and raw milk products is a serious public health concern. There is an abundance of scientific data and evidence to support the above statement. . . . To eliminate this serious public health concern, pasteurization is the most reasonable regulatory option to be used on raw milk, including certified raw milk and raw milk products. Pasteurization makes milk and milk products safe and this is a fact.

FDA3-005561. At least 18 other state agencies submitted comments to the same effect.[15] Private organizations, including the American Academy of Pediatrics[16] and others,[17] also submitted comments in support of milk pasteurization.

More important than the sheer number of commenters was the powerful scientific evidence that FDA collected establishing that raw milk constitutes a significant public

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[15] No states were in favor of the interstate distribution of raw milk. Agencies in favor of taking action against raw milk included: The Mississippi State Department of Health, *see* FDA3-002560-61; The National Association of State Departments of Agriculture, *see* FDA3-002564; The State of Nevada Division of Health, *see* FDA3-002566; The State of Maine Department of Human Services, *see* FDA3-002576; The Iowa Health Department, *see* FDA3-005552-53; The State of Indiana Board of Health, *see* FDA3-0002618-19; The Tennessee Department of Agriculture, *see* FDA3-005371; The State of Kansas Department of Health and Environment, *see* FDA3-005387; The State of New York Department of Health, *see* FDA3-005389; The State of Kansas, State Board of Agriculture, *see* FDA3-005499; The State of Minnesota Department of Agriculture, *see* FDA3-005501; The State of Missouri, Division of Health, *see* FDA3-005503; The State of New Mexico Health and Environment Department, *see* FDA3-005508-09; The Colorado Department of Health, *see* FDA3-005527-28; The State of Nebraska, *see* FDA3-005530; The State of Wisconsin Department of Health and Social Services, *see* FDA3-005538; The State of Wisconsin Department of Agriculture, Trade & Consumer Protection, *see* FDA3-005812-13; and the Arizona Department of Health Services, *see* FDA3-005557-58.

[16] *See* FDA3-002421. *See also* FDA3-000032 ("[T]he past few years we have witnessed an increasing number of illnesses and deaths associated with the increasing use of raw milk as a 'health food'. Unfortunately, the parents of innocent children fall prey to the advertising which asserts that raw milk is a safe food for infants."); and FDA3-005395-99 (letter from American Academy of Pediatrics, noting that the effects of raw milk "can be devastating to both children and adults," and enclosing materials).

[17] See FDA3-002410; FDA3-002411; FDA3-002412-20; FDA3-002422; FDA3-002440-50;FDA3-002452-53; FDA3-002463; FDA3-002569; and FDA3-002613-14.

health risk. For instance, the record reflects that the Centers for Disease Control and Prevention ("CDC") had concluded as of 1983 that raw milk was "inherently unsafe." *See* FDA3-000083. In support of its conclusion, the CDC prepared a detailed "Q&A" document (FDA3-000084-90), which stated, *inter alia*, that "[n]umerous investigations of outbreaks have demonstrated that [victims of foodborne illness] were significantly more likely to have consumed unpasteurized milk than were non-ill persons matched by such factors as age, sex, and neighborhood of residence . . . ."). Likewise, the CDC explained that it could "conceive of no practical way raw milk can assuredly be safely marketed." *See id.* at FDA3-000088. This was because:

> [m]ilk, collected aseptically from a normal mammary gland, should contain only the small numbers of bacteria that colonize the teat canal. However, even under the best of conditions, some of the feces and soil that collect on the cows' flanks, teats and udder end up in the milk and increase the bacterial load. The intrinsic presence of bacteria in mastitic milk which passes the visual inspection on the streak plate, and circulating organisms such as S. dublin in asymptomatic septicemic cattle (J Am Vet Med Assoc 1975;166:279), also contribute to the contamination level of raw market milk.

*Id*. The CDC also described the population most at risk from exposure to milk-borne pathogens: "[m]ilk is often given to infants, the elderly, persons with cancer, and other persons who have less resistance to infection by ingested organisms than has the general population. Raw milk can be particularly dangerous to such individuals." *Id*. at FDA3-000089. *See also* FDA3-005535-36 (Assistant Surgeon General describing risks of raw milk in correspondence to FDA).

The seriousness of the risks posed by raw milk were highlighted repeatedly in the record. For instance, in an article entitled "Invasive *Salmonella dublin* Infections

Associated with Drinking Raw Milk," the author examined patients hospitalized at a VA hospital during the course of a year. *See* FDA3-005520-24. The author found that *Salmonella dublin* is exceptionally virulent, and its invasiveness "was manifested by a high incidence of bacteremia . . ., metastatic infections . . ., and death." *Id.* at FDA3-005523.[18] The record contains voluminous other clinical and epidemiological data telling the same story.[19] For instance, the record included a summary of milk-borne disease outbreaks from between 1923 and 1949. *See* FDA3-001532-1674. During most of this period, milk was not typically pasteurized (*see* FDA3-002529), and between those years, state public health authorities attributed 813 deaths and 42,084 illnesses to milk-borne illnesses. *See* FDA3-001532; *see also* FDA3-002546-51 (describing several other more recent outbreaks associated with raw milk).

As California was the only state with significant distribution of raw milk at the time (*see Public Citizen II*, 653 F. Supp. at 1231), the administrative record also contains extensive information on milk-borne outbreaks in that state,[20] including a report

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[18] In conclusion, the author noted, "It is ironic that our patients, and presumably most others who drink raw milk, chose this product because they believed it to be healthier than pasteurized milk. Furthermore, they believed the raw milk was safe to drink because it was 'certified' and sold with the approval of various government agencies . . . . [I]t is important to reiterate that heat treatment (pasteurization) is the only reliable way to ensure that milk is not contaminated by Salmonella." FDA3-005480.

[19] According to a study published in the Journal of Food Protection (FDA3-002529-41), there were "abundant health hazards" associated with the consumption of milk before pasteurization was common, but a dramatic decrease thereafter. "Either, raw milk or certified raw milk has usually been the vehicle" of modern salmonellosis outbreaks in the United States. *Id.* at FDA3-002531. *See also* FDA3-002594-603 (article entitled "Raw Milk and Human Gastrointestinal Disease: Problems Resulting from the Legalized Sale of 'Certified Raw Milk'"); FDA3-000030-31.

[20] The administrative record also contains data on raw milk-related illnesses from many other states. *See, e.g.*, Campylobacterosis Associated with Consumption of

(continued...)

prepared by the California Department of Health on two outbreaks of salmonellosis. *See* FDA3-0001865-98. This report noted a significant association between occurrences of salmonellosis in California and the consumption of raw milk ("[o]f 38 cases from whom completed comprehensive food histories were obtained, 24 (or 63%) used raw milk") and concluded that the "pasteurization of milk provides the highest attainable level of consumer protection against milkborne disease." *See* FDA3-001873; FDA3-001865. A separate report, also prepared by the California Department of Health (*see* FDA3-005427-98), concluded that nearly all outbreaks of milkborne diseases in California were related to unpasteurized milk.[21] *See id.* at FDA3-005428; *see also* FDA3-002378-81 (1979 study published in the British Medical Journal, reporting that the consumption of raw milk was associated with 44 of the 113 cases of *Salmonella dublin* infections in California between 1971 and 1975); FDA3-002357; and FDA3-002358-60.

Following the court's order in *Public Citizen II,* FDA published its proposed rule to ban the interstate shipment of unpasteurized milk. *See* Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 52 Fed. Reg. 22340 (June 11, 1987) ("Proposed Rule"). In response, FDA received numerous comments, all but three

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[20](...continued)
Unpasteurized Milk, Disease Control Newsletter, Minnesota Department of Health, Vol. 8, No. 6, 1981. FDA3-001420-21; *see also* FDA3-002384-85; FDA3-002386-89; FDA3-002390-91; FDA3-002542; FDA3-002583; FDA3-005398 (reports describing outbreaks of salmonellosis and other diseases associated with raw milk).

[21] The administrative record also includes an extensive report prepared by a team of UCLA researchers summarizing documenting the risks of raw milk. *See* FDA3-005738.128-5811. *See also* FDA3-002423-36 (report on an Arizona outbreak concluding that "[m]ilk-borne transmission of disease rarely occurs if the milk is pasteurized, but it remains a significant problem where this is not a regular practice" (*id.* at FDA3-002432)).

of which "favored the proposed rule on the basis that the risks associated with consuming raw milk, including certified raw milk,[22] outweigh any benefits from its consumption." *See* Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 52 Fed. Reg. 29509, 29511 (August 10, 1987) ("Final Rule"). *See, e.g.,* FDA3-018299 (comment from American Academy of Pediatrics ("Pasteurization, together with appropriate dairy standards of cleanliness, remains the primary protection of children against milk-borne diseases."))[23]; FDA3-018611 (comment from CDC ("We believe that the Federal government should take a leadership role in preventing the morbidity and mortality now caused by raw milk by banning the interstate sale of raw milk.")).[24]

**2. FDA's Decision to Issue the PHSA Regulation Reflects Reasoned Decision Making.**

**a. FDA Reasonably Concluded That Raw Milk Presents a Significant Public Health Threat.**

In light of the overwhelming evidence described above, FDA found the record "demonstrate[d] an association between the consumption of raw milk and the outbreak of disease." *See* 52 Fed. Reg. 29511.[25] FDA also found the record demonstrated "an

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[22] The *Public Citizen II* court described "certified raw milk" as unpasteurized milk produced by methods that comported with the standards established by the American Association of Medical Milk Commissions, a private trade organization comprised of major producers of certified raw milk in the United States in 1987. *Public Citizen*, 653 F. Supp. at 1231 n.2.

[23] *See also* FDA3-018297-98; FDA3-018302-14 (amicus brief submitted by the American Academy of Pediatrics in *Public Citizen II).*

[24] *See also* FDA3-018610.

[25] *Citing* FDA3-000008-13; FDA3-005738.133-005811; FDA3-005426-33; FDA3-008009-13; FDA3-008177-78; FDA3-005493-95; FDA3-018055-58; FDA3-005477-81; (continued...)

association between the consumption of certified raw milk and the outbreak of disease, particularly among consumers who are young, elderly, or infirm." *Id.*[26]

As FDA stated in the Final Rule, its findings paralleled the conclusions of a study published in the Journal of the American Medical Association that "the role of unpasteurized dairy products, including raw and certified raw milk, in the transmission of disease has been established repeatedly." *Id.*[27] Particularly persuasive to FDA were statistics collected by the California Department of Health Services ("CDHS") on the incidence of *Salmonella dublin* ("*S. dublin*") infections. *Id.* at 29511-12. FDA summarized these statistics as follows:

> [CDHS] has reported that 50 percent of all the S. dublin infection cases reported in California in 1984 involved the use of certified raw milk. According to CDHS, no other risk factor has been prevalent among cases. For example, even though S. dublin is host adapted to cattle, only a small percent (15 percent or less) of cases report use of either lightly cooked or uncooked beef or beef products. CDHS concluded that the relative risk of contracting S. dublin is 158 times greater for those Californians who consume certified raw milk than for those who do not drink any form of raw milk. CDHS considered this relative risk 'extremely large and among the largest obtained in any epidemiologic investigation.'

*Id*. (emphasis added).

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[25](...continued)
FDA3-000083-90; FDA3-005498; and FDA3-000007-10.

[26] *Citing* FDA3-000008-13; FDA3-005738.133-005811; FDA3-005426-33; FDA3-008009-13; FDA3-008177-78; FDA3-005493-95; FDA3-018055-58; FDA3-005477-81; FDA3-000083-90; FDA3-005498; FDA3-000007-10; and FDA3-018637-40.

[27] *Citing* FDA3-005426-33; and FDA3-000007-10.

**b. FDA Reasonably Concluded That Careful Production of Raw Milk Does Not Eliminate the Public Health Threat.**

As set forth in the Final Rule, FDA concluded that "[r]aw milk, no matter how carefully produced, may be unsafe." *Id.* at 29512. This is because "[e]xaminations of cattle and of milk handlers can be done only at intervals. Consequently, pathogenic organisms may enter the milk during these intervals and be transmitted to humans before the presence of the organisms or the existence of a disease condition in cattle or handlers is discovered." *Id.* FDA found further "it has not been shown to be feasible to perform routine bacteriological tests on the raw milk itself to determine the presence or absence of all pathogens and thereby ensure that it is free from infectious organisms." *Id.* FDA concluded that programs to ensure the safety of raw milk, such as certification, "does not provide a reliable index of whether milk or milk products are contaminated with pathogenic bacteria." *Id.*[28] In light of the foregoing considerations, FDA concluded that careful production practices or certification processes alone can "provide no assurance that raw milk is free of *Salmonella* and other harmful organisms." *Id.*

**c. FDA Reasonably Concluded That There are No Demonstrable Health Benefits from Drinking Raw Milk.**

Upon review of the scientific evidence in the record, FDA reasonably concluded that "[t]he theoretical health benefits of raw milk have never withstood scientific scrutiny." *Id.* at 29512. Conversely,"the fact that raw milk presents a substantially greater inherent risk of infectious disease has been documented repeatedly." *Id.* After reviewing the "[n]umerous articles [that] have reported that pasteurization has either no

[28] *Citing* FDA3-005376-85.

effect or practically no effect on the major nutrients in milk," FDA concluded that the health risks posed by raw milk "outweigh any alleged health benefits that may arise from consuming raw milk and certified raw milk." *Id*. at 29512-13.[29]

**d. FDA Reasonably Rejected Alternatives to a Ban.**

FDA considered, and rejected, the use of warning labels on raw milk as an alternative to an outright ban. *See Id.* at 29513. Every commenter on the Proposed Rule (including supporters of raw milk) opposed such labeling. *Id*. FDA ultimately rejected the warning-label alternative because, *inter alia*, "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 food use."[30] As such,

> consumers are not generally expected to take any additional steps to reduce the potential risk and are poorly equipped to assess the likelihood of infection. The infirm, the elderly, and the young are particularly susceptible to serious risks of infection presented by consuming raw milk and raw milk products and, in many cases, may not have the ability or the opportunity to understand the risks identified in labeling.

*Id*.[31]

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[29] *Citing* FDA3-008164-71.

[30] FDA also concluded that the use of "[e]xisting screening technologies [is] an inadequate alternative to pasteurization as a means of ensuring the safety of milk and milk products." *Id.* at 28513. FDA found that available technologies were unable to identify pathogens quickly enough (given the short shelf-life of milk) and the existence of multiple organisms that may pose human health concerns posed major obstacles to relying on a system designed to detect microorganisms. Ultimately, FDA agreed with the conclusion of the American Academy of Pediatrics that "[t]he fact is that there is no laboratory test available that will simultaneously and instantaneously screen for brucellosis, tuberculosis, salmonellosis, listeriosis . . . ." *Id.* (quoting FDA3-018299).

[31] *See also, e.g.,* FDA3-018610-11 ("Even with a warning label, some consumers tend to assume that any product being sold is safe because public health authorities would not allow a truly unsafe product to be sold."); and FDA3-018278 ("Raw milk is a

(continued...)

Plaintiffs allege in Count One of their Amended Complaint that the PHSA Regulation is arbitrary and capricious because, in their view, while milk introduced into interstate commerce must be pasteurized, unpasteurized juice requires only a warning. *See* Am. Compl. ¶¶ 80-81. Plaintiffs reference to the juice regulations misses the mark, primarily because most juice must, in fact, be pasteurized (or subject to an equivalent process). Although it is true that, in 1998, FDA promulgated 21 C.F.R. § 101.17, under which a warning label was required for unpasteurized juice, this regulation was effectively superseded three years later. *See also* 66 FR 6138-01, 6143 ("The agency mandated the use of warning label statements on juice largely as an interim step to establishing the [Hazard Analysis and Critical Control Point ("HACCP")] regulation.") FDA's juice HACCP regulations, issued in 2001, require processors to pasteurize juice products (or use equivalently effective processes. *i.e.,* "control measures that will consistently produce, at a minimum, a 5 log (*i.e.*, 105) reduction . . . in the pertinent microorganism."). *See* 21 C.F.R. § 120.24.[32] As there is no inconsistency in the FDA's treatment of milk and juice, plaintiffs' reference to the juice HACCP regulations does not support their argument.

Furthermore, there is no reason why the rules for juice and the rules for milk must be identical, because the risks posed by juice and milk are not the same. *See*

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[31](...continued)
ready to eat food whose qualities could vary from day to day. It is questionable whether any warning which might be drafted could override other labeling on the product . . . . The warning would probably generate confusion on the part of the public rather than act as a deterrent."). *See also* FDA3-018624; 018232; and 018285.

[32] Like the PHSA Regulation, the juice HACCP regulations exempt purely local sales by retailers. *See* 21 CFR § 120.3(j)(2)(ii) (excluding activities of retail establishments from definition of "processing").

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138, 6141 (January 19, 2001) ("While there may be some fundamental principles, such as basic sanitation procedures, that apply to both the production of milk and juice, the products are vulnerable to different hazards.").

* * *

In sum, it cannot reasonably be argued that the agency failed to articulate an explanation establishing a "rational connection between the facts found and the choice made." *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Nor does the record indicate that FDA made a "clear error in judgment" in deciding to ban interstate shipments of raw milk (*see Citizens to Preserve Overton Park*, 401 U.S. at 416), or that there was no "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43; *Falk*, 452 F.3d at 953.[33] Plaintiffs' APA challenge to the PHSA Regulation should be denied.

### E. Plaintiffs' Challenge to the Milk Standard of Identity Regulation is Not Justiciable.

The bulk of plaintiffs' claims center on the PHSA Regulation and its perceived effects on the interstate distribution of raw milk. But in addition to producing and evaluating the administrative record leading to promulgation of the PHSA Regulation,

[33] If the Court somehow concludes that FDA has failed to consider all the relevant factors, or if the Court believes it cannot evaluate the agency's action on the basis of the record before it, the "proper course" for the Court, "except in rare circumstances, is to remand to the agency for additional investigation or explanation." *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

FDA has also produced the administrative record with respect to the promulgation of the Milk Standard of Identity Regulation.[34]

If the Court does not grant defendants' motion for summary judgment, this Court should nevertheless refrain from entertaining plaintiffs' claims with respect to the Milk Standard of Identity Regulation because those claims are not justiciable. To FDA's knowledge, the government has not initiated a single enforcement action with respect to interstate distribution of raw milk based on a violation of the Milk Standard of Identity Regulation. Nor has FDA cited that regulation in *any* of the Warning Letters that it has issued related to the interstate distribution of raw milk. In fact, since promulgation of the PHSA Regulation in 1987, FDA has relied entirely on the PHSA Regulation to ensure that milk delivered into interstate commerce has been pasteurized. The agency has no present intention to alter that practice.[35]

In its Opinion, this Court determined that the test for determining whether a claim is ripe includes, among other things, the requirement that plaintiffs allege that they have "sustained *or are in immediate danger* of sustaining some direct injury as a result of the challenged statue or official conduct." Opinion at 41 (*citing Public Water Supply Dist. No. 10 of Cass County, Mo. v. City of Peculiar, Mo.*, 345 F.3d 570, 573 (8th Cir. 2003) (emphasis in original)). Thus, there must be a link between the alleged injury and the specific law being challenged. Here, although defendants respectfully disagree that plaintiffs have met the injury requirement even for challenging the PHSA Regulation, it

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[34] *See* FDA-000001 through 001932; FDA2-000001 through 003455; and FDA4-000001 through 000898.

[35] Indeed, it stands to reason that this is one reason why the *Public Citizen II* court ordered FDA to promulgate the PHSA Regulation.

is plain that plaintiffs cannot, *in any event*, plausibly claim that they have suffered or are in immediate danger of sustaining an injury from the 38-year-old Milk Standard of Identity Regulation that has never been enforced in connection with the interstate distribution of raw milk.

Plaintiffs' challenge to the Milk Standard of Identity Regulation is not ripe for an additional reason. In finding that plaintiffs' Amended Complaint alleged ripe claims at the motion to dismiss stage, this Court described plaintiffs' constitutional claims as purely legal and concluded that defendants failed to identify any "potentially important facts that are missing with respect to the purported application of the regulations to these plaintiffs . . . ." Opinion at 38-39. Yet, facts are missing for their challenge to the Milk Standard of Identity Regulation. Before considering an action to enforce a violation of the Milk Standard of Identity Regulation - which, as noted above, has not happened to date - the agency must consider the specific package labeling at issue and whether the interests protected by 21 U.S.C. § 341 are implicated (*i.e.*, whether consumers' interests are threatened because of a lack of honesty and fair dealing).[36] The need to evaluate the regulation in the context of specific product labeling is another reason why the regulation should not be subject to a facial challenge like the one plaintiffs bring now. *See Public Water Supply Dist. No. 10 of Cass County, Mo. v. City of Peculiar, Mo.,* 401 F.3d 930, 932 ("One kind of advisory opinion is an opinion "advising what the law would be upon a hypothetical state of facts.") (*citing Preiser v. Newkirk,* 422 U.S.

[36] By comparison, knowledge of the product label is not essential to the PHSA Regulation, because it proscribes the introduction into interstate commerce of all raw milk in final package form, no matter how it is labeled.

395, 401 (1975)). The Court should not be required to assess the impact of every possible variation in milk labeling when it is highly speculative whether FDA will seek to bring a case under the Milk Standard of Identity Regulation, let alone one against these plaintiffs.

For all these reasons, this Court should reject plaintiffs' challenges to the Milk Standard of Identity Regulation as unripe.

## VI. The PHSA Regulation and the Milk Standard of Identity Regulation Are Not Unconstitutional.

This section constitutes defendants' supplemental briefing in support of their renewed motion to dismiss for failure to state a claim upon which relief can be granted.[37] The Regulations are, beyond reasonable question, constitutionally sound. Indeed, in order to grant the plaintiffs' requested relief under any of their constitutional claims, this Court would have to dramatically expand the scope of existing jurisprudence under the Fifth Amendment. Not a single case recognizes the exotic rights that plaintiffs seek to have this Court establish. Indeed, plaintiffs admit forthrightly that their claims are novel and perhaps unprecedented. *See* Pl's Resist. to Defs.' MTD 3 ("Resist.") ("As a case of first impression, this Court will be issuing a decision that will have profound impacts across the country."). No court in the nation has even come close to accepting the constitutional theories pressed by plaintiffs, and their entreaty to dramatically expand the scope of the Fifth Amendment should be denied.

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[37] As set forth in the Motion to Dismiss, a complaint should be dismissed under Rule 12(b)(6) for failure to state a claim if plaintiff can prove no set of facts in support of the claim that would entitle the plaintiff to relief. *See* MTD 4.

As discussed in Section V, *supra*, FDA promulgated the PHSA Regulation on the basis of overwhelming scientific evidence that the delivery of raw milk into interstate commerce posed an unacceptable threat to public health. Even if there were some plausible argument that people have rights guaranteed under the Constitution to eat and drink anything they want (and there is not), such rights would not trump the government's paramount interest in protecting the public health. *See, e.g., Oregon-Wash. R. & Nav. Co. v. Washington*, 270 U.S. 87, 95 (1926) ("the 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") (*quoting Minnesota Rate Cases*, 230 U.S. 352, 406 (1913)).

As an initial matter, it is unnecessary for this Court to entertain the constitutional claims posed by plaintiffs because FDA has announced in the Administrative Determination that, absent exceptional and unforseen circumstances, it will not enforce the PHSA Regulation against consumers who purchase raw milk solely for personal consumption. *See* Admin. Determination 9 ("FDA has not brought enforcement actions against individual consumers in the past and, subject to the considerations described above, has no present intent to do so in the future."). In light of FDA's pronouncement, any newly created constitutional right would have no practical effect with respect to consumers of raw milk and a holding recognizing such right would therefore be unnecessary. *See, e.g., Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring) ("It is not the habit of the court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case.") (internal

quotations omitted)[38]; *see also Spector Motor Svc., Inc. v. McLaughlin*, 323 U.S. 101, 105 (1944) ("If there is one doctrine more deeply rooted than any other in the process of constitutional adjudication, it is that we ought not to pass on questions of constitutionality . . . unless such adjudication is unavoidable.").

The fact that FDA has reserved the right to enforce the PHSA Regulation against sellers and distributors of raw milk has no relevance to any plaintiffs' constitutional claims.[39] Plaintiffs have not proffered *any* theory on how commercial actors could possess rights guaranteed by the Constitution to engage in the interstate sale of raw milk.

Should this Court determine that it is necessary to reach the constitutional issues raised by plaintiffs, for the reasons set forth below, each of their arguments should be rejected and the constitutionality of the PHSA Regulation upheld. Plaintiffs' arguments apply equally to the Milk Standard of Identity Regulation, and the constitutionality of that regulation should be upheld on the same grounds.[40]

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[38] *See also Ashwander*, 296 U.S. at 347. ("The Court will not formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied.") (internal quotations omitted).

[39] *See* Admin. Determination 9 ("FDA . . . intends to continue to direct its limited resources to enforcement actions against those who produce and/or distribute raw, unpasteurized milk in interstate commerce.").

[40] As set forth in Section V.E, *supra*, to its knowledge, FDA has never brought an enforcement action under the authority of the Milk Standard of Identity Regulation and is unlikely to do so in the foreseeable future. Accordingly, that regulation is of modest significance in this litigation and the discussion in this section is therefore weighted towards the PHSA Regulation.

### A. The Regulations Do Not Implicate the Constitutional Right to Travel.

In Count Two of their Amended Complaint, plaintiffs allege that the Regulations burden their "fundamental right to travel from one State to another State in a manner that is free from unnecessary burdens." Am. Compl. ¶ 104. Their claim fails first and foremost because the Regulations simply do *not* burden the right to travel in any material sense. People who desire raw milk may still cross state lines like anyone else; they simply must leave their raw milk behind. This is not an inconvenience of any constitutional significance. Indeed, under plaintiffs' logic, it might follow that the entire federal regulatory regime with respect to the regulation of food might be unconstitutional to the extent it might prevent persons from taking unlawful food products across state lines. *See, e.g.,* 21 C.F.R. §§ 100 through 169 (regulations pertaining to food for human consumption promulgated pursuant to the FDCA). This is quite clearly not the case.

Specifically, the Regulations do not violate Plaintiff Donnelly's,[41] Allen's,[42] Heckman's,[43] Miller's[44] or Rose's[45] right to travel, because those plaintiffs wish only to travel to other states to purchase raw milk and return home. These plaintiffs are merely barred by the Regulations from purchasing in interstate commerce that which is illegal to buy in their home states; their right to travel remains unaffected.

The remaining plaintiffs wish to enter into commercial transactions that have been proscribed by Congress in the PHSA and FDCA and by FDA through regulations

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[41] *See* allegations regarding Plaintiff Donnelly at Am. Compl. ¶¶ 6-9.
[42] See allegations regarding Plaintiff Allen at Am. Compl. ¶¶ 10-13.
[43] *See* allegations regarding Plaintiff Heckman at Am. Compl. ¶¶ 14-17.
[44] *See* allegations regarding Plaintiff Miller at Am. Compl. ¶¶ 18-21.
[45] *See* allegations regarding Plaintiff Rose at Am. Compl. ¶¶ 22-25.

clearly authorized under the PHSA and the FDCA. Plaintiff Wagoner operates a business called "Athens Locally Grown" in Georgia, which purchases and receives raw milk from out of state and distributes it to Georgians.[46] (It is illegal to sell raw milk for human consumption in the State of Georgia. *See* Am. Compl. ¶ 27; *see also* GEORGIA CODE. ANN § 26-2-242. It is also illegal to ship unpasteurized milk for human consumption into Georgia from another state. *See* GEORGIA CODE. ANN. § 26-2-244(a).) Plaintiff Cooper is a customer of Wagoner's who *does not even allege* a desire to travel.[47] Likewise, plaintiff Buck does not allege that he desires to travel, but simply wishes to introduce raw milk into interstate commerce by selling it to visitors from other states.[48] No constitutional right to travel protects these commercial actors Wagoner and Buck.

As described in defendants' Motion to Dismiss, the constitutional right to travel involves something else entirely. *See* MTD 22-23. 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 v. Roe*, 526 U.S. 489, 500-02 (1999) (citations

[46] *See* allegations regarding Plaintiff Wagoner at Am. Compl. ¶¶ 30, 32.
[47] See allegations regarding Plaintiff Cooper at Am. Compl. ¶ 31.
[48] See allegations regarding Plaintiff Buck at Am. Compl. ¶¶ 36-43.

and quotation marks omitted)).[49] The constitutional right to travel is used to strike down "state legislation that had a negative impact on travel between the various States," but is inapplicable to "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"); *see also id.* n.3 ("Except for cases dealing with federal restrictions on international travel . . . , the Court's right-to-travel jurisprudence has focused on a fundamental issue of federalism, the extent to which States may restrict American citizens' right to travel within their nation.")

The Regulations do not materially 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. As defendants argued in their Motion to Dismiss, "to 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).

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

There is no fundamental right, protected by the Due Process Clause of the Fifth Amendment, to introduce raw, unpasteurized milk into interstate commerce. Neither, as

[49] In their opposition to the motion to dismiss, plaintiffs' offer a weak rejoinder to defendants' citation to *Saenz*, noting that *Saenz* itself dealt with only the third component. *See* Resist. 40. This does not change the fact that no known case has ever recognized a right to travel with raw milk, or any other article, in tow.

defendants discussed in their Motion to Dismiss, is there a fundamental right to consume raw milk. *See* MTD 24-27 (addressing claims raised in plaintiffs Amended Complaint at ¶¶ 117-118, 135, 143-144.)).

As discussed in Section V, *supra*, the vast weight of scientific opinion holds that raw milk is an inherently dangerous product, in that it is a disease vector for many dangerous microorganisms, including *Salmonella* and *Listeria*. Based on these scientific conclusions, FDA promulgated the PHSA Regulation banning the interstate distribution of raw milk.

This Court should not recognize for the first time a fundamental right to receive or deliver raw milk into interstate commerce. First, such a right would fly directly in the face of Congress' delegated power to regulate interstate commerce. *See* U.S. Const. art. 1, § 8 ("The Congress shall have Power . . . To regulate Commerce . . . among the several States . . . ."). Furthermore, as discussed in the Motion to Dismiss, to prevail, a plaintiff must show both that the claimed fundamental rights "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." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (citation and quotation marks omitted). Plaintiffs have not come close to satisfying that standard.

No known reported case has ever recognized a fundamental right to consume a particular type of food, and it is wishful thinking on plaintiffs' part to contend that such a right could exist with respect to an inherently dangerous product like raw milk. Plaintiffs' response that there must be a fundamental right to raw milk because the early settlers did not drink pasteurized milk is obtuse. *See* Resist. 44 ("Indeed, a pasteurization plant

in the United States was not required from the time Jamestown was settled in 1607 until . . . 1973."). In that early era, modern sanitation standards had yet to be invented and microorganisms remained undiscovered.

The regulation of interstate shipments of raw milk is a matter that should be left to Congress and the political process. Plaintiffs' remedy with respect to a law they do not like should not be a change to the Constitution, but to petition Congress to change the law.

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

As discussed in the Motion to Dismiss, the interests asserted by plaintiffs are not fundamental rights, and thus the Regulations are not subject to strict scrutiny. Therefore, the Regulations are subject to a rational basis review. *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."). As set forth in Section V, *supra*, the PHSA Regulation rests on an extensive record supporting the conclusion that the interstate shipment of raw milk encourages the spread of communicable disease. Therefore, the PHSA Regulation easily survives rational basis review. The Milk Standard of Identity Regulation was promulgated following the compilation of a significant administrative record on the subject of milk labeling. *See id.*

Plaintiffs' response is that rational basis review applies only to statutorily-created classifications. *See* Resist. 63. This is wrong. Rational basis review applies to statutes *and* their implementing regulations. *See, e.g., Bowman v. United States*, 564 F.3d 765, 776 (6th Cir. 2008) ("The regulation easily survives rational basis review."); *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1112 (9th Cir. 2004) ("The statute and regulations clearly survive rational basis review because they rationally promote a legitimate state interest."); *Whittle v. United States*, 7 F.3d 1259, 1262 (6th Cir. 1993) ("Unless a statute or regulation impinges upon a fundamental right or involves a suspect classification, a minimal level of scrutiny is applied under the rational basis test."). In any event, even if plaintiffs were correct, it would not help their case. If rational-basis review applies only to statutes, the PHSA and FDCA would be subject to such review. Review of the Regulations would be confined to the standards set forth in the APA (*i.e.*, arbitrary and capricious, and *ultra vires* review).

Plaintiffs are also wrong that the rationality of the Regulations are undermined by the fact that some states allow sales of raw milk. *See, e.g.*, Resist. 36 ("[I]f the alleged interest behind [the Regulations] is to prevent citizens from having access to raw milk, that interest is not served because there are 28 states that allow the purchase of raw milk and/or raw dairy products.") Plaintiffs' observation is of no consequence, because the PHSA is not designed to thwart the *intra*-state spread of disease. *See* Section 361(a) of the PHSA Act, 42 U.S.C. § 264(a) ("The Surgeon General . . . is authorized to make and enforce such regulations . . . to prevent the introduction, transmission, or spread of communicable diseases . . . from one State or possession into any other

State or possession.").[50] FDA cannot be faulted if the Regulations fail to achieve a goal that was never intended for the PHSA or the FDCA.

Likewise, contrary to plaintiffs' argument, the fact that the government has not banned every potentially dangerous article does not render the Regulations irrational. *See* Resist. 37 (the interest of prohibiting "'potentially dangerous products' . . . is not served by the multitude of products that can be freely transported across state lines"). FDA proceeded in accordance with the PHSA, which addresses the spread of disease. Other agencies, such as the Consumer Product Safety Commission, the EPA, the Department of Transportation, etc., regulate other types of products. The fact that the world may remain a dangerous place does not obviate the goals of the PHSA; the same holds true with respect to the requirements for food labeling under the FDCA.[51] This Court should reject plaintiffs' "novel proposition that regulations failing to address all of the causes of a problem are, for that reason, arbitrary and capricious", for it is a "well-established rule that regulations need not remedy all evils, or none." *Louisiana ex rel.*

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[50] While intra-state commerce *may* be regulated under the PHSA, such regulation is designed to prevent the inter-state spread of disease, which approach FDA did not take in this case. *See, e.g.*, *Louisiana v. Mathews*, 427 F. Supp. 174 (E.D. La. 1977) (upholding inter- and intra-state ban of commerce in small turtles because of *Salmonella* risk). FDA opted against this approach and adopted the less restrictive means of regulation, concluding "that State and local authorities may be better situated to deal with the public health problems attributable to unpasteurized milk." 52 Fed. Reg. 29513.

[51] Moreover, several of the examples of "dangerous" products cited by plaintiffs on page 37 of their Resistance to the Motion to Dismiss *are* in fact regulated and subject to lawful restrictions. Most "medicines" (*i.e.,* drugs) for instance, may not be introduced into interstate commerce unless approved by FDA (*see* 21 U.S.C. §§ 355(a) and (j)), and FDA regulates interstate commerce in tobacco products. *See* 21 U.S.C. § 387(a)*, et seq.* Likewise, it is axiomatic that alcohol may not be freely transported across many state lines.

*Guste v. Verity*, 853 F.2d 322, 332 (5th Cir. 1988), *quoting Railway Express Agency, Inc. v. New York*, 336 U.S. 106, 110 (1949).

Next, plaintiffs argue, repeatedly, that the PHSA is irrational because FDA has allegedly designated raw milk itself as a "communicable disease" or an "illness." *See, e.g.*, Resist. 56 ("it defies common sense to define 'milk' *per se* as an 'illness' for purposes of regulating a 'communicable disease.'"). In so arguing, plaintiffs misread the law and misconstrue FDA's actions. As discussed above, Section 361(a) of the PHSA provides authority to promulgate regulations "to prevent the introduction, transmission, or spread of communicable diseases." 21 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. *See* 52 Fed. Reg. 29509, 29511.

Plaintiffs are also incorrect that FDA should have used a "less stringent means of regulating raw milk," such as warning labels stating that the products are unpasteurized. First of all, under a rational basis review, an agency is not required to employ the "least restrictive means" to accomplish its goal. *See Heller*, 509 U.S. at 330. Moreover, as discussed in Section V, *supra*, in promulgating the PHSA Regulation, FDA specifically considered, *and rejected*, the use of warning labels for legitimate public health reasons.

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

As defendants discussed in their Motion to Dismiss, plaintiffs are incorrect that FDA's regulations prohibiting the interstate sale and distribution of unpasteurized milk for human consumption violate the "separation of powers/non-delegation doctrine." *See*

MTD 19-22. Plaintiffs' claim fails, *inter alia*, because they have failed entirely to make the requisite showing that Congress' enactment of the PHSA 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). For this reason and as otherwise set forth already in our Motion to Dismiss, plaintiffs' claims under the Non-Delegation Doctrine should be dismissed.

## CONCLUSION

For the foregoing reasons, 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 in Section V, *supra.*

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 May 11, 2011.

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