

Milking It: Raw Milk and its Various Legal Challenges

Jessica MacAuley

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I. Introduction

Fluid milk from cows is an important component to the American diet. Since 1973, the United States Food and Drug Administration has declared that any milk sold in interstate commerce for human consumption must be pasteurized.¹ Since that time, the federal government has warned of the severe health problems that can be associated with drinking unpasteurized milk, known as “raw milk.”² While it is illegal to ship raw milk in interstate commerce, consumption of raw milk is legal in all fifty states. Each state now has varying levels of regulation regarding raw milk.³ Some states, such as Pennsylvania, allow for raw milk to be bought in retail states.⁴ Other states, like New Jersey, forbid the sale of raw milk completely.⁵

Despite the warnings of the federal government, a group of Americans claim raw milk to be a curative elixir that offers health benefits, better taste, a lower environmental impact and an economic boom to small farmers.⁶ Raw milk drinkers who live in states where the sale of raw milk is prohibited have developed semi-legal and even illegal

¹ Mandatory Pasteurization for all Milk and Milk Products in Final Package Form Intended for Direct Human Consumption, 21 C.F.R. §1240.61 (1987) [hereinafter “Pasteurization Regulation”] (“pasteurized” is defined as ‘every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table... 145 °F for 30 seconds, 161°F for 15 seconds, 191°F for 1 second, 204°F for .05 seconds and 212°F for .01 seconds”).

² See, Food and Drug Administration, *The Dangers of Raw Milk: Unpasteurized Milk Can Pose Serious Health Risks*, available at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079516.htm>.

³ See, Weston Price Foundation, *Summary of Raw Milk Statutes and Administrative Codes* (2004), available at <http://www.realmilk.com/milk-laws-1.html>.

⁴ 31 P.S. §646 and §652.

⁵ N.J. Rev. Stat. § 24:10-57.17 (1987).

⁶ Farm-to-Consumer Legal Defense Fund, *Learn More-Raw Milk*, available at <http://www.ftcldf.org/raw-milk.html>.

methods of obtaining raw milk. Some consumers engage in contractual relationships such as cow or herd-shares⁷, while others buy milk through virtual farmer's markets and black market drop-off points. In addition, some consumers have taken the FDA to federal court challenging the pasteurization requirement is against their due process rights and is arbitrary and capricious.⁸ This paper will explore these various avenues of obtaining raw milk, the likelihood of success of various court cases and the pros and cons of the raw milk movement.

II. The Regulation of Milk Through American History

A. The Road to Pasteurization

Milk from cows is an abundant source of essential minerals and vitamins necessary for human growth and development.⁹ Since the time of the Jamestown colonies, the inhabitants of the United States have relied on cow's milk as a nutritional additive to their diet.¹⁰ Contributing to the America's reliance to dairy, large areas of the United States provide an ideal home for pasturing cattle.¹¹ This combination of pastureland and nutritional potency created an American relationship with milk that continues to this day. As America has grown from small settlements to large urban

⁷ Weston A. Price Foundation, Cow Shares, *Herd Shares, Farm Shares*, available at <http://www.realmilk.com/cowfarmshare.html>.

⁸ *Farm-to-Consumer Legal Defense Fund, et al v. Sebelius, et al.* 734 F. Supp. 2d 688 (N.D.Iowa 2010).

⁹ Stuart Patton, *MILK: IT'S REMARKABLE CONTRIBUTION TO HUMAN HEALTH AND WELL BEING*17 (Transaction Publishers 2004).

¹⁰ Ron Schmid, *THE UNTOLD STORY OF MILK: THE HISTORY, POLITICS AND SCIENCE OF NATURE'S PERFECT FOOD: RAW MILK FROM PASTURE-FED COWS* 25-25 (New Trends Publishing 2009).

¹¹ See Patton, *supra* note 9, at 18.

centers, the nature and supply of food production has changed. In the dairy industry, the Industrial Revolution led to contaminated milk and a dirty milk health crisis.

The War of 1812 changed the nature of feeding dairy cows when the importation of liquor from Europe ceased.¹² Cities began to establish their own distilleries to produce liquor, creating an abundance of grain mixed with water. Enterprising distilleries then began feeding this ‘distillery slop’ to dairy cattle in large pens next to the distilleries.¹³ These dairies were large and extremely dirty with animal waste and dead cows creating hot beds for disease. These diseases were easily transmitted into the cow’s milk. Reports from that time show a large spike in infant death from tuberculosis and diarrhea, much of which was blamed on the milk produced by distillery cows.¹⁴ The increase in infant mortality led to two movements among scientists and consumers to change the safety of milk; the certified milk movement and the pasteurized milk movement.¹⁵

Pasteurization refers to the process discovered by Louis Pasteur that “uses the application of heat to destroy human pathogens in foods.”¹⁶ Pasteurization advocates believed all raw milk had the potential to be unsafe and that the best way to ensure public safety was to require of all milk be pasteurized.¹⁷ The certified milk movement believed

¹² See Schmid, *supra* note 10, at 32.

¹³ *Id.* at 32.

¹⁴ *Id.* at 35.

¹⁵ Morris E. Potter, *Unpasteurized Milk: The Hazards of a Health Fetish*, 252 JAMA 2048 (1984).

¹⁶ International Dairy Foods Association, *Pasteurization: Definition and Methods*, available at, <http://www.idfa.org/news--views/media-kits/milk/pasteurization/> .

¹⁷ The driving force behind the pasteurization movement in the early 1900’s was a businessman named Nathan Straus who campaigned for over 30 years for the pasteurization of the New York City milk supply. Mr. Strauss campaigned vigorously in the United States and Europe for uniform pasteurization and is quoted as saying, “There can be no question but that the entire milk supply everywhere ought to be

the health and cleanliness of the cows and farms would ensure quality, healthful milk.¹⁸ Certified milk supporters advocated for a medical milk commission that would oversee milk production standards in the farm, processing and shipping of milk.¹⁹ They criticized milk pasteurization claiming it would hurt the nutritional content, diminish the flavor and allow for the furtherance of unsanitary conditions in milk production.²⁰

During the 1920's and 30's, state and local authorities created varying or concurrent pasteurization and certification ordinances to deal with the still pervasive food poisoning by milk.²¹ In an attempt to create uniform regulations, the United States Public Health Service began developing model milk ordinances which a state or local authority could adopt.²² By 1938, while the number of illness was on the decline, “milkborne outbreaks constituted twenty-five percent of all disease outbreaks due to infected foods and contaminated water.”²³ Advances in technology continued to make the milk consumed by Americans safer, but regulation over milk was strictly local due to the local nature of milk economies. Prior to the 1970's, the majority of Americans purchased their

pasteurized, not only that intended for infants, since the use of raw milk for adults is almost equally fraught with danger.” See Schmid, *supra* note 10, at 69.

¹⁸ *Id.* at 53-55.

¹⁹ See Schmid, *supra* note 10, at 53-55.

²⁰ See Potter, *supra* note 15, at 2048.

²¹ *Id.*

²² U.S. Department of Health and Human Services, *Grade “A” Pasteurized Milk Ordinance* (2007) available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSMModelDocuments/PasteurizedMilkOrdinance2007/ucm063836.htm#foreword>.

²³ *Id.*

milk through local home delivery.²⁴ This milk was typically produced within a short distance, therefore state regulation was preferable. However, once the retail sale of milk in stores became widespread and local delivery of milk became a thing of the past,²⁵ the Federal Food and Drug Administration began rulemaking procedures to set federal standards for the safety of milk.

B. FDA Regulation Banning the Interstate Sale of Unpasteurized Milk

On October 10, 1973, after a notice and comment period, the United States Food and Drug Administration (“FDA”) promulgated its first federal standard requiring milk to be pasteurized.²⁶ The regulation found that, “while raw milk produced under carefully controlled conditions is relatively safe, pasteurization assures the destruction of pathogenic bacteria that may be present.”²⁷ The regulation was stayed, however, after receiving several objections from producers of “certified raw milk” in December of 1974.²⁸ The regulation was stayed until 1984 when a health group, Public Citizen, filed a petition in the D.C. Circuit Court asking the Secretary to ban all sales of raw milk.²⁹ On January 14, 1985 the Court ordered the FDA to “publish within 60 days a proposed rule reflecting its decision.”³⁰

²⁴ Dennis A. Shields, *Consolidation and Concentration in the U.S. Dairy Industry*, 3 Cong. Research Serv. (2003).

²⁵ *Id.*

²⁶ Food and Drug Administration, *Department of Health and Welfare Milk and Cream*, 21 C.F.R. 18, 38, Fed. Reg. 27, 924.

²⁷ *Id.* at 27,921

²⁸ *Public Citizen v. Heckler, Secretary of Health and Human Services*, 602 F.Supp. 611, 612 (U.S.D.C. D.C. 1985).

²⁹ *Id.* at 612-613.

³⁰ *Id.* at 614.

After prolonged rulemaking and multiple hearings, on August 10, 1987 the FDA issued its final rule banning the sale of unpasteurized milk in interstate commerce.³¹ In its final rule, the FDA rejected raw milk certification because, “certification does not provide a reliable index of whether milk or milk products are contaminated with pathogenic bacteria.”³² The FDA reasoned that the overall ban was appropriate because illness or death from the consumption of raw milk cannot be completely eliminated through clean practices. Nor could it be prevented through proper use of raw milk. Rather, the product itself was determined to be unsafe, rather than the practices of farmers.³³

The Pasteurization Regulation states that, “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 that has not been pasteurized...”³⁴ The regulation was enacted under Federal Drug, and Cosmetic Act, 21 U.S.C. §§301-399a³⁵

³¹ See Pasteurization Regulation, *supra* note 1.

³² Department of Health and Human Services: Final Rule: Requirement Affecting Raw Milk for Human Consumption in Interstate Commerce, 52 FR 29509, 29512 (1987) [hereinafter “Pasteurization Rule”].

³³ *Id.* at 29513.

³⁴ See *Id.* at 29513. (“In light of the opinions expressed in the comments; the documented risks presented by raw milk, including raw milk and raw milk products; the fact that such products are, indeed, shipped in interstate commerce; and the likelihood that a pasteurization requirement for such products in interstate commerce will result in some benefit to the public health, FDA has concluded that the use of Federal authority and resources to eliminate health problems caused by the interstate shipment of raw milk is justifiable.”)

³⁵ The main directive on which the FDA focused was §393(b)(2) which directs the FDA to “protect the public health by ensuring that – foods are safe, wholesome, sanitary and properly labeled.”

and Public Health Service Act, 42 U.S.C. §§201-300ii.³⁶ The FDA reasoned that since most raw milk products were sold and consumed intrastate, individual states and localities would be best suited to promulgate regulations regarding raw milk sales.³⁷

C. If Raw Milk Is So Dangerous, Why Would Anyone Drink It?

With the federal government and state health agencies warning consumers that unpasteurized milk is unsafe, why would consumers still drink it? While individual motivations are unknown, many advocates publicize several reasons for drinking raw milk. First, and most vocally, advocates declare that pasteurization destroys important health benefits of milk. Moreover, many drinkers consume raw milk as a way to ‘check out’ of the industrial food system and engage in the local food movement. Lastly, advocates claim that raw milk sales can also have a strong economic benefit for small dairy farmers hoping to extract themselves from the highly regulated milk pricing system.

1. Health Claims of Raw Milk Advocates

Raw milk drinkers make various health claims regarding the nutritional value of unpasteurized milk.³⁸ Some raw milk advocates support a cellular theory of disease, which proposes that disease arise from microorganisms that live within the cells of the body, which are related to a particular condition.³⁹ In simplified terms, our bodies contain the microorganisms already and we become ill when these organisms become unstable. In order to prevent disease, health must be created on the inside instead of blocking

³⁶ 42 U.S.C. §264(a) (authorizes the FDA to “make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one state to another”).

³⁷ See Pasteurization Rule, *supra* note 24, at 29513.

³⁸ See Farm-to-Consumer Legal Defense Fund, *supra* note 6.

³⁹ David E. Gumpert, *THE RAW MILK REVOLUTION: BEHIND AMERICA’S EMERGING BATTLE OVER FOOD RIGHTS* 50 (Chelsea Green Publishing Company 2009).

outside organisms.⁴⁰ Raw milk consumers believe that the bacteria found in raw milk helps their cells remain in balance and actually increases overall health.⁴¹ Raw milk drinkers who ascribed to this theory believe that pasteurization kills the bacteria necessary for vital health and that they want the bacteria and living organisms contained in raw milk in order to create a more balanced immune system.⁴²

In addition to killing organisms, raw milk advocates believe that pasteurization kills essential vitamins and minerals in milk.⁴³ During the pasteurization process, water and fat-soluble vitamins are destroyed. Raw milk advocates claim that Vitamins B6, B12 and Vitamin C are destroyed by the pasteurization and homogenization process.⁴⁴ Advocates also propose that essential enzymes contained in milk – lactase, galactase, lactoperoxidase, lactoferrin – are broken down and almost completely eliminated during the heating process.⁴⁵ Also, essential fatty acids such as omega-3 and conjugated linoleic acid are eliminated in milk that has fat removed.⁴⁶

⁴⁰ Walene James, *Pasteurian Germ Theory v. Bechamp Cellular Theory*, available at <http://www.whale.to/v/germ.htm>.

⁴¹ See Gumpert, *supra* note 39, at 52. (Raw milk provides a perfect source for the “seeding and feeding” of these diverse populations of living bacteria. The average American diet is practically devoid of living bacteria...our immune systems have suffered as a direct result.”)

⁴² National Public Radio, *What’s Healthier: Raw Milk or Regulation?* (2010), available at <http://www.npr.org/templates/story/story.php?storyId=128912799>. (“I reject the government’s rules for pasteurization, homogenization; all these things on my food. And I want E.coli, listeria, salmonella in my food.”)

⁴³ See Gumpert, *supra* note 39, at 52.

⁴⁴ See NOFA Massachusetts Raw Milk Network, *Why is Raw Milk So Good?*, available at <http://www.nofamass.org/programs/organicdairy/rawmilk.php>.

⁴⁵ See Schmid, *supra* note 2, at 106-107.

⁴⁶ See NOFA, *supra* note 35.

2. Market Dimensions of Raw Milk

In addition to health benefits, many raw milk drinkers advocate removing themselves from the industrial food system and becoming part of the local food movement. While local food has no agreed upon definition, it is a concept that encompasses the values of limited travel and interaction with the person who is raising your food.⁴⁷ Scholars have also described the local food movement based on the motivation of consumers involved. These motivations include, “[a] 1) sense of connection, 2) quality, 3) environmental impact, and 4) political and social support for a particular type of agriculture.”⁴⁸ Examples of local food sales include farmers markets, community supported agriculture and the sale and consumption of raw milk.⁴⁹ Food safety is also benefit proclaimed by local food activists. As the industrialized food system grows, local food advocates argue that the contamination of food products increases.⁵⁰ Many outbreaks of illness due to food contamination have links to the industrial food system, causing contamination to spread quickly across state lines.⁵¹

⁴⁷ Steve Martinez, *Local Food Systems: Concepts, Impacts and Issues*, USDA Economic Research Service Report No. 97 (May 2010), in Susan Schneider FOOD, FARMING AND SUSTAINABILITY READINGS IN AGRICULTURE LAW 665 (Carolina Academic Press 2011).

⁴⁸ Marne Coit, *Jumping on the Next Bandwagon: An Overview of the Policy and Legal Aspects of the Local Food Movement*, 4 J. Food. & Poly's 45, 48 (2008). See also, United States Department of Agriculture, *Know Your Farmer, Know Your Food*, available at http://www.usda.gov/wps/portal/usda/knownyourfarmer?navtype=KYF&navid=KYF_MISSION. (The website lists as its goals to, “support local farmers, strengthen rural communities, promote healthy eating, and protect natural resources”).

⁴⁹ See Martinez, *supra* note 47, at 666.

⁵⁰ Nathan M. Trexler, *Market Regulation: Confronting Industrial Agriculture's Food Safety Failures* 17 *Widener L. Rev.* 311, 345 (2011).

⁵¹ *Id.* (This includes mad-cow disease, spinach, red peppers, and peanut butter).

Estimates of consumers who drink raw milk on a regular basis are approximately 500,000.⁵² Similar to other agriculture industries, technological advancement in dairy production have led to higher milk yields from a smaller amount of cattle. These technological advances rely on concentration – having the cows in limited area producing high quantities of milk.⁵³ The effect of this has been a sharp decrease in the number of farm operations and a sharp increase in the volume of milk per cow head.⁵⁴ The United States Department of Agriculture estimates that in 1980 there were approximately 340,000 dairy farms.⁵⁵ By the year 2009 that number had shrunk to approximately 65,000.⁵⁶ At the same time, in 1965 the average cow was producing 8,000 pounds of milk per year, in 2009 that number was 21,000.⁵⁷ The practical effect of these concentrations and farm practices is a dwindling number of small dairy farmers.

Raw milk advocates see their business model as a way to save the small dairy farmer from bankruptcy. The Farm-to-Consumer Foundation estimates that a small dairy farm with 15 head of cows, selling raw milk at \$5 per gallon, will have a total gross income of \$40,320.⁵⁸ Newspapers also carry anecdotal evidence of small dairies that

⁵² Kerry Hannon, *Raw Milk is Gaining Fans, but Science Says It's Dangerous*, U.S. News (March 20, 2009), available at <http://health.usnews.com/health-news/family-health/articles/2009/03/20/raw-milk-is-gaining-fans-but-the-science-says-its-dangerous>.

⁵³ See Shields, *supra* note 24, at 6-7.

⁵⁴ *Id.*

⁵⁵ United States Department of Agriculture, *Economic Effects of U.S. Dairy Policy and Alternative Approaches to Milk Pricing*, 23 (July, 2004), available at <http://www.usda.gov/documents/NewsReleases/dairyreport1.pdf>.

⁵⁶ See Shields, *supra* note 3, at 6.

⁵⁷ *Id.*, at 7.

⁵⁸ See Farm-to-Consumer Foundation, *Raw Milk Micro Economics*, available at www.farmtoconsumer.org/.../Raw%20Milk%20Micro%20Economics%20Presentation%20-Handout.pdf.

were facing bankruptcy and now are functioning at a profit thanks to a conversion to raw milk sales.⁵⁹ Farmers interested in the sale of raw milk in states where raw milk sales are illegal have pushed their lobbied their legislature to pass positive regulation for raw milk dairies.

An example of this is New Jersey,⁶⁰ where shortly after the FDA banned the interstate sale of raw milk, the New Jersey legislature passed a bill banning the sale of raw milk within the state.⁶¹ To circumvent the ban New Jersey consumers of raw milk were crossing the border into Pennsylvania to purchase. As Ed Wengryn of the New Jersey Farm Bureau testified, “[raw milk] can actually be a growing niche for farmers who want to do it.”⁶² On March 14, the New Jersey Assembly voted to approve Assembly No. 743, legalizing raw milk sales, in large part due to the economic gains it would have for the state of New Jersey.⁶³

⁵⁹ See David E. Gumpert, *Got Raw Milk? Patients are either ignoring their doctors or lying to them*, 26 *The Boston Globe* (March 23, 2008) (“This change has made a remarkable turnaround in the fortunes of Oake Knoll Ayshire farm, which she has had been going downhill...”).

⁶⁰ Assembly No. 743 State of New Jersey 214th Legislature Proposed Bill A-743 (“Permit the sale of raw milk under certain conditions and establishes the raw milk permit program.”)

⁶¹ See N.J. Rev. Stat. § 24:10-57.17 (1987) (“No person shall sell, offer for sale, or distribute to the ultimate consumer any milk or cream that is not pasteurized”).

⁶² Tamara Scully, *New Jersey and Raw Milk: Perfect Together* (February 21, 2011), available at <http://www.countryfolks.com/ME2/Audiences/dirmod.asp?sid=&nm=&type=Publishing&mod=Publication&s%3A%3AArticle&mid=8F3A7027421841978F18BE895F87F791&tier=4&id=956A1241BAAF480B82AFEECAD9A2712B&AudID=90DC82AE125D4E708CD1E3ED9DA80CA2>

⁶³ See *Dimaio Proposal to Allow Raw Milk Passes Assembly* (March 17, 2001) available at <http://www.politickernj.com/45973/dimaio-proposal-allow-raw-milk-passes-assembly>. See also, Assemblywomen Connie Wagner, *Assembly Panel Advances Wagner Bill to Aid New Jersey Farmers by Allowing for Sale of Raw Milk*, (February 10, 2011) (“Currently hundreds of families are crossing our border into other state to purchase raw milk...just outside New Jersey. With hundreds of families drinking hundreds of gallons of raw milk a year, at roughly \$7 a gallon, this legislation will bring a welcome boost of revenue to New Jersey farmers and our economy”).

D. Raw Milk, No Matter How Clean, is a Bad Idea-The Response of Federal Regulators and the Dairy Industry to Raw Milk Claims

Despite raw milk advocates many claims, federal regulators and the dairy industry actively campaign against raw milk. The Center for Disease Control reports that from 1998 to 2005, there were 39 reported outbreaks of illness caused by raw milk or raw milk products consumption.⁶⁴ The FDA's dominant concern is the spread of Salmonella, E.Coli O157:H7, Campylobacter jejuni, listeria monocytogenes.⁶⁵ The FDA notes that milk is an ideal host environment for these strains of bacteria. Because the FDA believes that even the cleanest dairy has a possibility for these bacteria, raw milk is inherently dangerous.⁶⁶ In addition, children are at a higher risk of becoming sick from these products. FDA believes that the "freedom of choice" argument is flawed when you give children raw milk because a child given raw milk lack understanding.⁶⁷ As the FDA's John Sheehan states, "if children know that raw milk might make them very ill, cause them to lose their kidneys or even kill them, would they choose to drink it."⁶⁸

The FDA stance on raw milk is important to producers because it sets the stage for limited consumer demand. In fact, FDA explicitly rebuts the local food movement philosophy of food quality stating, "many Americans have adopted a 'back to nature' philosophy...embracing the idea that locally produced and minimally processed foods are

⁶⁴ The FDA believes this number is under representative because not all outbreaks are reported. See John F. Sheehan, *On the Safety of Raw Milk (With a Word About Pasteurization)* 5 (2005), available at <http://www.cfsan.fda.gov/~ear/milksafe/milksa5.htm>

⁶⁵ See, Food and Drug Administration, *The Dangers of Raw Milk: Unpasteurized Milk Can Pose Serious Health Risks*, available at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079516.htm>.

⁶⁶ See Pasteurization Rule, *supra* note 32, at 29513.

⁶⁷ Sheehan, *supra* note 64, at 31.

⁶⁸ *Id.*

more nutritious.”⁶⁹ The CDC’s website also includes a section containing three videos of “real stories” about raw milk consumption. These stories focus on educated women who suffered dire health consequences from drinking raw milk.⁷⁰

In addition to federal regulators, dairy producers and federations are opposed to the sale of raw milk. The National Milk Producers Federation sees the sale of raw milk as “a silly and dangerous notion”⁷¹ and has lobbied state legislatures and Congress to pass food safety legislation limiting or banning the sale of raw milk.⁷² The National Dairy Council advises against the consumption of raw milk and warns that the trend of states allowing further sale of raw milk products will have a negative effect on public health.⁷³ The increase in raw milk sales had led the Dairy council to warn, “it is important to increase public awareness of the microbiological safety hazards of raw milk and certain dairy products manufactured using raw milk and recommend that only pasteurized milk be consumed.”⁷⁴ As part of the mainstream dairy systems, these federations and

⁶⁹ Food and Drug Administration, *Raw Milk May Pose Health Risk*, available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm232980.htm>

⁷⁰ Mary McGonigle-Martin, Center for Disease Control and Prevention, *Real Stories of the Dangers of Raw Milk*, available at <http://www.cdc.gov/foodsafety/rawmilk/raw-milk-videos.html>. (“The risk from drinking raw milk isn’t a tummy ache for a few days or diarrhea and vomiting that goes away. The risk is that the pathogen could kill you”).

⁷¹ Jerry Kozak, National Milk Producers Foundation, *Rubbed Raw*, available at <http://nmpf.org/latest-news/ceo-corner/jun-2010/rubbed-raw>. (“[The raw milk] debate is too often is shrouded in a kind of fantastic wishful thinking, both from a health and an economic standpoint”).

⁷² *Id.*

⁷³ National Dairy Council, *Misperceptions Regarding Dairy Foods: A Review of the Evidence*, Dairy Council Digest (January/February 2010), available at <http://www.nationaldairyCouncil.org/Research/DairyCouncilDigestArchives/Pages/dcd81-1Page1.aspx>.

⁷⁴ *Id.*

producers would be economically injured not only from negative press from an outbreak of illness, but also if more consumers purchase milk from unconventional sources.

The dairy industry's image is also effected by raw milk proponent claims that their milk is less healthful than unpasteurized milk. Federal regulators and dairy producers contradict claims that raw milk is healthier than pasteurized milk.⁷⁵ In its rulemaking determination, FDA concluded that in addition to pasteurization causing no significant health loss, the risk of illness related to the drinking of raw milk far overshadowed any alleged health benefits.⁷⁶ The National Dairy Council claim that the pasteurization and homogenization process does not create any "meaningful" change in vitamins and mineral and in addition, the addition of vitamin D to pasteurized milk allows for greater absorption of key nutrients such as calcium and phosphorus.⁷⁷ Proponents of raw milk contest even those raw milk illnesses that are reported by the CDC claiming that the link between the milk and illness was never proven or that the illness was caused by something other than the milk.⁷⁸

⁷⁵ See Pasteurization Rule, *supra* note 24, at 29512 ("numerous articles...document that pasteurization has little or no effect on milk's protein, minerals, riboflavin, fat, carbohydrate, niacin, panthoenic acid, vitamin B6, vitamin A, vitamin D, vitamin, E, and vitamin K.")

⁷⁶ See *id.*, at 29513.

⁷⁷ *Misperceptions Regarding Dairy Foods: A Review of the Evidence*, Dairy Council Digest Volume 81 Number 1. January/February 2010. See also, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D and Fluororide* (National Academy Press, 1997).

⁷⁸ Weston A. Price Foundation, *Response to the FDA: A point-by-point rebuttal to the Anti-Raw Milk Powerpoint Presentation by John F. Sheehan* 5 (2007) available at www.realmilk.com/documents/SheehanPowerPointResponse.pdf. ("Many outbreaks in which raw milk has been "implicated" are almost certainly attributable to another cause...statistical associations with raw mlk may arise in cases where the actual cause of the outbreak is contact with animals or their manure, person-toperson contact, or the consumption of other foods sold by raw milk product street vendors").

III. Consumer Pathways Around the Pasteurization Regulation

Despite aggressive campaigning by federal regulators and the dairy industry, thousands of raw milk consumers consume the beverage every day. Although the sale of raw milk may be illegal in some states, it is not illegal in any state to consume raw milk. Drinkers of raw milk use this loophole in a variety of ways to obtain raw milk. Several ways exist for consumers to obtain the milk, but regulators have been closing the noose on some of these methods. In addition, some a group of consumers have filed suit to declare Pasteurization Regulation illegal and in excess of FDA's authority.

A. Cow Shares and how states are closing that loophole

A cow or herd share is an agreement between a farmer and a consumer where a fee is charged for the boarding and care of the cow.⁷⁹ The cow share member then has rights to obtain milk from the cows because he is considered the "owner"⁸⁰ In some states, the legislature has pass explicit regulation that allow for cow share agreements.⁸¹ But other state legislatures have remained silent.⁸² This silence has led to regulations moving to stop cow-shares from occurring and pursuing those who do in court.

⁷⁹ Weston A. Price Foundation, *Cow Shares, Herd Shares, Farm Shares*, available at <http://www.realmilk.com/cowfarmshare.html>.

⁸⁰ *Id.*

⁸¹ See N.C. Gen. Stat. §130A-279 (" 'sale' or 'sold' shall mean any transaction that involves the transfer or dispensing of milk and milk products or the right to acquire milk and milk products through barter or contractual arrangement or in exchange for any other form of compensation including, but not limited to, the sale of shares or interest in a cow, goat or other lactating animal.") See also, Colo.Rev.Stat. §25-2.2-117 ("(1) the acquisition of raw milk from cows or goats by a consumer for use or consumption by the consumer shall not constitute the sale of raw milk and shall not be prohibited if... (b) the milk is obtained pursuant to a cow share or a goat share.")

⁸² The Farm-to-Consumer Foundation offers farmers a Cow Share College and Goat-Share University Program via the telephone where farmers can receive advice and practical knowledge on how to begin their own herd-share. See *Cow Share College*, available at http://www.farmtoconsumerfoundation.org/cow_share_college.php.

In Maryland, the Court of Special Appeals approved the state’s regulation against cow-shares in the case of *Oyarzo v. Maryland Department of Health and Mental Hygiene*.⁸³ In *Oyarzo*, a dairy farmer had sent a proposed “Bovine Sale and Agistment Agreement” to the Maryland Department of Health and Mental Hygiene to receive pre-approval.⁸⁴ The agreement would leave Oyarzo with the responsibility of boarding, caring and milking the herd of cows, while those who bought a proportional interest would be entitled to receive the raw milk from the cows.⁸⁵ The Health Department rejected his request and instead effectuated new regulations that would forbid agistment arrangements that, “provides funding to feed or care for a cow or cows, and obtains raw milk in return.”⁸⁶ The Maryland Court of Special Appeals upheld this decision by the Department both to decline Oyarzo’s agreement and to approve the regulation banning the herd share arrangement as a method to receive raw milk.⁸⁷

It is important to note that the *Oyarzo* decision does not hold that an agistment agreement is illegal or violates the Maryland statute against the sale of raw milk. Rather, the court reasoned that the Secretary is delegated authority to establish regulations regarding milk products and that these regulations should be upheld as long as they are,

⁸³ *Oyarzo v. Maryland Dept. of Health and Mental Hygiene*, 189 Md. App. 264 (August 26, 2009).

⁸⁴ *Id.* at 269. An agistment is a “bailment in which a person, for a fee, allows animals to graze on his or her pasture; the taking in of cattle or other livestock to feed at a per-animal rate.” BLACK’S LAW DICTIONARY 73 (8th Ed. 2004).

⁸⁵ *Id.*

⁸⁶ *Oyarzo*, *supra* note 83, at 270

⁸⁷ See Md. Code Regs. 10.15/06.06(F)(1) (2006).

“consistent with the statutory scheme.”⁸⁸ The court held that the Oyarzo agreement had the effect of raw milk being distributed to consumers and, therefore, the Secretary was within his rights to regulate. The courts upholding of the regulation has essentially made cow-share arrangements illegal in the State of Maryland.⁸⁹

Similar to Maryland, the sale of raw milk is illegal in the state of Iowa.⁹⁰ In 2009, the Iowa Department of Agriculture decided to take action against the cow-share arrangements which they had been informed were taking place across Iowa.⁹¹ Charles Freitag⁹² and Mindy Slippy (“Iowa Plaintiffs”) had entered into separate contracts with an Amish farmer to purchase a share of a dairy cow.⁹³ The Iowa Plaintiffs would periodically visit the Amish farmer, bring their own bottles and caps and obtain milk

⁸⁸ See *Oyarzo supra* note 83, at 293. (citing *Medstar Health v. Md. Health Care Commission*, 376 Md. 1, 23, 827 A.2d 83 (2003)).

⁸⁹ Maryland has a bill currently in the House that would eliminate this House Bill 1080 which would, “Exempting from regulation the sale of raw milk and raw milk products from specified producers directly to the final consumer; conditioning the exemption on a requirement that the consumer has an ownership interest in specified animals; requiring the ownership interest in specified animals to be acquired by a specified contract; establishing that the exemption does not apply to specified sales of milk and milk products; etc.” See, MD. House Bill 1080, available at, <http://mlis.state.md.us/2009rs/billfile/hb1080.htm>.

⁹⁰ Iowa Code §§ 191.103 (2009). (“Only Grade “A” pasteurized milk and milk products shall be sold to the final consumer, or to restaurants, soda fountains, grocery stores, or similar establishments...”).

⁹¹ See *2009 Dairy Advisory Board Teleconference Minutes*, available at <http://www.iowaagriculture.gov/DairyProductsControl/2009DAIRYADVISORYBOARDMINUTES.pdf>. (“Margaret Thomsen, remarked on the cow sharing (raw milk). They are aware of a case and working on action against it. If you hear of any of this going on in Iowa, let the department know... simply stated raw milk – cow sharing is illegal. Thank you to the Department of Ag & Attorney General’s office for the enforcement”).

⁹² Charles Freitag has since left the lawsuit. See Order re Motion for Dismissal, *Charles Freitag, et al. v. Bill Northey, Secretary Iowa Department of Agriculture and Land Stewardship*, No. EQ-cv-67958 ¶15 (Dist. Ct. Iowa, Linn Cty, January 25, 2010).

⁹³ See Complaint, *Charles Freitag, et al. v. Bill Northey, Secretary Iowa Department of Agriculture and Land Stewardship*, No. EQ-cv-67958 ¶15 (Dist. Ct. Iowa, Linn Cty, January 25, 2010).

from “their” cow.⁹⁴ In February of 2009, the Iowa Department of Agriculture and Land Stewardship sent the Amish farmer an enforcement letter stating that he was in violation of Iowa Code 192.103 by selling the Iowa Plaintiff’s raw milk.⁹⁵ The letter gave the Amish farmer 10 days to terminate the arrangement or he would lose his milking permit.⁹⁶ The Amish farmer cut off his agreement with the Iowa Plaintiffs, who then filed suit in the Iowa District Court for Linn County on January 25, 2010.⁹⁷ The case is currently in the discovery process. Since the Iowa Department of Agriculture did not create a new regulation, as they did in Maryland, the court in this case may uphold the cow-share agreement since there is no specific regulation against them.

B. The Black Dairy Market- Buyers Clubs and Farmers Markets

Some consumers, whether because of proximity to farms or fear of becoming contractually involved with a farmer, choose less direct routes to receive raw milk. Membership in buyers clubs and online farmer’s markets give consumers in states where raw milk sale is illegal an avenue for obtaining the product. In general, a buyer’s club usually functions through a membership process that is closed to the public.⁹⁸ Even in states where raw milk can be obtained legally, consumers use buyers clubs to get their supply. This is especially true in urban centers, such as New York City, where consumers

⁹⁴ *Id.* at, ¶20.

⁹⁵ *Id.* at, ¶25.

⁹⁶ *Id.* at, ¶26.

⁹⁷ See *Docket Report, Charles Freitag, et al. v. Bill Northey, Secretary Iowa Department of Agriculture and Land Stewardship*, No. EQ-cv-67958 ¶15 (Dist. Ct. Iowa, Linn Cty, January 25, 2010), available at <http://www.iowacourts.state.ia.us/ESAWebApp/TIndexFrm>.

⁹⁸ See David G. Cox, Farm-to-Consumer General Counsel, Address at the Pennsylvania Association for Sustainable Agriculture Annual Conference, *The Raw Milk & Local Food Revolution* 33-36 (Slideshow Presentation) (February 5, 2010).

are unable to travel to the farm⁹⁹ and instead become members of clandestine milk clubs.¹⁰⁰ It is also true in states such as Arizona where raw milk is legal, but the United Dairywomen of Arizona, which has a majority of Arizona dairy farmers as members, does not allow their members to sell it.¹⁰¹ Similarly in Massachusetts, the Department of Agricultural Resources has been in a battle with several raw milk dairy clubs and has sent several “cease and desist” letters to their farms to stop their practice of having one member of a club travel and then bring the milk back to a pick-up stop.¹⁰²

In an effort to curb these raw milk “black markets,” the FDA has initiated enforcement action against dairy farmers who have sold raw milk in interstate commerce.¹⁰³ Organic Pastures Dairy Company,¹⁰⁴ a California certified raw milk dairy, had been shipping raw milk and raw milk products to all fifty states, labeling the milk as “pet food.”¹⁰⁵ In 2007, the FDA filed a criminal action against Organic Pastures claiming

⁹⁹ In New York raw milk sales are only directly to a consumer on the farm where the milk is produced, in addition a sign must be posted reading, “NOTICE: Raw milk sold here. Raw milk does not provide the protection of pasteurization.” See 1 N.Y.C.R.R. 2.3.

¹⁰⁰ See Joe Drape, *Should This Milk Be Legal*, New York Times Company, Sec. F, Column O (August 8, 2007).

¹⁰¹ See Cary Aspinawall, *Laws Unable to Cow Raw-Milk Fans; FDA Says Beverage is Dangerous to Drink*, The Arizona Republic, Pg. 1A (November 17, 2005).

¹⁰² Brian R. Ballous, *Raw-milk Advocates Rally for Access to their Drink*, Boston Globe, available at, http://articles.boston.com/2010-05-11/news/29287924_1_raw-milk-nonpasteurized-milk-farms.

¹⁰³ Most recently FDA has filed a complaint for permanent injunction against Rainbow Acres Farm in Kinzer, Pennsylvania for distributing misbranded raw milk in interstate commerce. See FDA News Release *FDA seeks permanent injunction against Pennsylvania Dairy*, available at, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm252727.htm>.

¹⁰⁴ See Organic Pastures Dairy Company, <http://www.organicpastures.com/index.html> (last visited April 26, 2011).

¹⁰⁵ See Joe Drape, *Should This Milk Be Legal*, New York Times Company, Sec. F, Column O (August 8, 2007).

they had introduced “misbranded food” into interstate commerce.¹⁰⁶ Organic Pastures pled guilty and entered into a plea agreement.¹⁰⁷

Concurrent with the criminal action, FDA filed a civil complaint asking for a permanent injunction against Organic Pastures from distributing raw milk. This injunction not only would forbid Organic Pastures from shipping raw milk again, but also sought to have all consumers of Organic Pastures sign an agreement not to distribute the milk out of California.¹⁰⁸ These agreements were designed to prevent a member of a buying club from buying milk from Organic Pastures, crossing state lines and distributing the milk.¹⁰⁹ The court granted FDA’s injunction, but struck down the proposed order which would make consumers sign an agreement, however, the court did approve of a requirement that Organic Pastures kept detailed records of purchasers of their raw milk and raw milk products.¹¹⁰ Organic Pastures Dairy’s website now has a legal disclaimer that they no longer ship raw milk across state lines.¹¹¹

The non-reluctance of state regulators to take action against illegal raw milk pathways is not surprising given the increase of raw milk publicity and sales. If the trend of raw milk consumption continues to grow, raw milk advocates can expect to see more

¹⁰⁶ See *United States v. Organic Pastures Dairy Company*, 708 F. Supp. 2d 1005, 1009 (E.D. Ca. 2010).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 1013-1014.

¹⁰⁹ *Id.* at 1014 (“Your honor...the reason we are asking for written statements for people that are going to resell is that those people, who are taking milk across state lines, now have knowledge and they are on notice that their conduct is illegal and that the FDA can proceed against those people”).

¹¹⁰ *Id.* at 1017-1018.

¹¹¹ <http://www.organicpastures.com/legal-notice.html> (“This strict policy is a result of a settlement agreement reached recently with the United State Government after the Government determined that OPDC had violated CFR 1240.61.”).

actions being brought against them. While cow-share agreements may contain recognized property rights that shield them from enforcement, the black market and virtual farmers markets will likely see more action against them. In recognition of this possibility, the Farm-to Consumer Legal Defense fund recently filed lawsuit in federal district court as a preemptive strike against the FDA and the Pasteurization Regulation.

C. A Challenge to 21 C.F.R. §1240.61, *Farm-to Consumer Legal Defense Fund v. Sebelius*.

The legal and illegal methods of raw milk sales have come to a head in a case before the District Court for the Northern District of Iowa.¹¹² Filed by the Farm-to-Consumer Legal Defense Fund against Secretary of U.S. Department of Health and Human Services, Kathleen Sebelius, the complaint represents several different types of plaintiffs engaged in raw milk sales or distribution. The first are the “direct purchaser plaintiffs” (“DPP”). The DPP are the private citizens who reside in the states where the sale of raw milk is illegal.¹¹³ The DPP, themselves, cross state lines into a state where consumer sale of raw milk is legal. They then purchase the milk and cross in their own state of residence to consume the milk.¹¹⁴ One plaintiff, Miller, is slightly different because he lives in a state where raw milk is legal, Pennsylvania, and crosses into a state where raw milk is illegal, Virginia, to consume the raw milk with his family.¹¹⁵

¹¹² See Plaintiff’s Complaint for Declaratory, Preliminary and Other Injunctive Relief, *Farm-to-Consumer Legal Defense Fund v. Kathleen Sebelius*, 2010 WL 186897, 110-CV-4018 (N.D. Iowa, filed February 18, 2010) [hereinafter Plaintiff’s Complaint].

¹¹³ *Id.* at ¶6-25

¹¹⁴ *Id.*

¹¹⁵ *Id.* at ¶20-21.

Next are the “principal and agent plaintiffs” (“PAP”). These plaintiffs operate a “virtual farmers market” where interested persons pay a membership fee to join an online buyers club.¹¹⁶ The PAP then cross into a state where purchase of raw milk is legal and then back into their state of residence to distribute the raw milk to the membership of the virtual club.¹¹⁷ Last is a plaintiff farmer who resides and sells raw milk in a state where it is legal, South Carolina, but knowingly sells raw milk to persons he knows have traveled from Georgia and North Carolina, states where raw milk sale is illegal.¹¹⁸

Plaintiff’s allege that the FDA’s interstate ban on raw milk (1) exceeds the FDA’s statutory authority and is arbitrary and capricious; (2) violates the Constitutional right to travel; (3) violates the Constitutional right to privacy; (4) violates the non-delegation doctrine; and (5) violates substantive due process.¹¹⁹ Plaintiffs do not focus their arguments on the reasons why they want to drink raw milk. Rather, they claim that the FDA regulations are designed not to keep the milk safe for consumption, but rather to protect the industrial subsidized dairy farming system.¹²⁰ Plaintiffs are private citizens who claim to want to remove themselves from that system.¹²¹ On August 18, 2010, Judge Bennet ruled in favor of the Farm-to Consumer Legal Defense Fund against the United

¹¹⁶ *Id.* at ¶26-35.

¹¹⁷ *Id.* at ¶33.

¹¹⁸ *Id.* at ¶36-43.

¹¹⁹ *Id.* ¶68-144

¹²⁰ Plaintiff’s Brief in Support of Resistance to Defendant’s Motion to Dismiss *Farm-to-Consumer Legal Defense Fund, et al v. Sebelius, et al.* 10-cv-4018 5 (June 15, 2010 USDC N.D. Iowa) [hereinafter Plaintiff’s Brief].

¹²¹ *Id.*

States motion to dismiss.¹²² In order for Plaintiff's to prevail, they will have to evidentiary hurdles. The first is achieving standing to sue and the second is proving that their due process or liberty interest has been violated by a federal regulation. Due to a measure of deference to administrative regulations, Plaintiff's will have an uphill battle in proving either of these past the motion to dismiss stage.

1. *Farm-to Consumer Legal Defense Fund v. Sebelius: Standing*

In order for plaintiff's to challenge an administrative regulation, they must first achieve standing. Standing can come from two sources, the statutory language of the regulation¹²³ or Article III of the U.S. Constitution.¹²⁴ To achieve Article III standing, plaintiffs must have suffered an "injury in fact" that is not hypothetical, there must be a causal connection between the injury and the action of the government, and the injury can be redressed by a decision for the plaintiffs.¹²⁵

The district court found that Plaintiff's had standing to oppose the regulations under Article III of the Constitution because they had a credible threat of injury.¹²⁶ The direct purchaser plaintiffs were found to have standing because their actions could be considered to be unpasteurized milk into interstate commerce, therefore, the court found

¹²² *Farm-to-Consumer Legal Defense Fund, et al v. Sebelius, et al.* 734 F. Supp. 2d 688 (N.D.Iowa 2010) [hereinafter FCLDF].

¹²³ See 5 U.S.C. §702. ("A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is intitled to judicial review thereof").

¹²⁴ U.S. CONST. art. III, §2, cl. 1. ("The Judicial Power shall extend to all cases...and to controversies").

¹²⁵ See *Lujan v. Defenders of Wildlife* 504 U.S. 555 (1992)

¹²⁶ See FCLDF, *supra* note 122, at 687-692. (Plaintiff Wagoner has the strongest case for standing before the court because the FDA has taken action against him. On October 15, 2009, after Wagoner had procured a shipment of raw milk in South Carolina, he was stopped in Georgia and forced to dump the raw milk he was carrying. Video footage of the dumping can be viewed at <http://www.youtube.com/watch?v=EMfQXxVAPgk> (Part 1) and <http://www.youtube.com/watch?v=wPey52Ybp0U&feature=related> (Part 2)).

that the FDA could be within their rights to bring an enforcement action against them.¹²⁷

While plaintiff's have survived the standing inquiry, they will still need to prove that the agency has caused them an injury. It should be noted that achieving standing in the motion to dismiss stage is a lower threshold than for the summary judgment phase.

Plaintiff's will have to prove injury under §706 of the Administrative Procedures Act and claim that the FDA has robbed them of a liberty interest and due process rights by not allowing them to purchase foods and threatening action against them "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law."¹²⁸

2. The Due Process Challenge-Enforcement Actions Against Consumers of Raw Milk

The Supreme Court has fashioned a three-prong test to determine whether an administrative action would violate due process rights in violation of the Constitution.

These factors are:

"First, the private interest that will be affected by the official action; second, the risk of erroneous deprivation of such interest through the procedures used, and the probable value, if any, of addition or substitute procedural safeguards; and finally, the Government interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail."¹²⁹

Plaintiff's claim that the first prong of this test has been violated because the Pasteurization Regulation denies them a "liberty" interest. Since the plaintiff's have not had any FDA judicial action against them, Plaintiff's claim that the FDA regulation has

¹²⁷ *Id.* at 686 ("Plaintiffs have standing to challenge the facial validity of a regulation notwithstanding the pre-enforcement nature of a lawsuit, where the impact of the regulation is direct and immediate and they allege an actual, well-founded fear that the law will be enforced against them")(citing, *Gray v. City of Valley Park, Mo.*, 567 F.3d 976, 984 (8th Cir. 2009)).

¹²⁸ 5. U.S.C. §706(2).

¹²⁹ *See Mathews v. Eldridge*, 424 U.S. 319, 355 (1976).

infringed on their basic constitutional right to, “travel across State lines; their right to feed themselves and their families the foods of their choice; their right to raise their families in accordance with their beliefs about food; and their right to have an agent of their choice deliver to them the food of their choice.”¹³⁰

The Supreme Court has held that, “the ‘liberty’ specially protected by the Due Process Clause includes the rights to marry, to have children, to direct the education and upbringing of one’s children, to marital privacy, to use contraception, to bodily integrity, and to abortion.”¹³¹ But the court has also warned of judicial restraint of accepting new fundamental ‘liberty’ rights because, “by extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action.”¹³² Plaintiff’s will need to convince the court that the right to purchase raw milk belongs in one of these liberty interest categories or expand the definition to of ‘liberty’ interest to include food choice.

3. Liberty Interest-The Right to Travel

In *Saenz v. Roe*, the Supreme Court upheld the constitutional “right to travel” and has held that states cannot impose regulation to restrict travel, create resident requirements designed to inhibit migration from one state to another or impose a penalty on persons traveling from one state to another.¹³³ However, the Supreme Court has not made this right absolute. For example, States may prevent a citizen from leaving the State

¹³⁰ See Plaintiff’s Complaint, *supra* note 109, at ¶52

¹³¹ See *Washington v. Glucksberg*, 521 U.S. 702,720 (1997).

¹³² See *Doe v. Miller*, 405 F.3d 700, 710 (8th Cir. 2005) (quoting “*Reno v. Flores*, 507 U.S. 292, 302 (1993)).

¹³³ *Saenz v. Roe*, 526 U.S. 489, 499 (1999).

if he has been convicted of a crime.¹³⁴ Courts have also upheld states prohibiting nonresidents from obtaining firearms licenses.¹³⁵ These cases demonstrate that courts have considered the Supreme Court's 'right to travel' interest to be balanced against a interests that states decide are legitimate. Court's have also not extended the 'right to travel' to federal regulation. For example in *Minnesota Senior Federation v. United States*, the Eight Circuit held that *Saenz* should be read as dealing with state prohibitions and that it does not refer to a federal regulation.¹³⁶

The Pasteurization Regulation does not prevent plaintiffs, or anyone, from traveling to a different state. Persons are free to go from state to state and are not prohibited from travel by any government regulation. While consumers are in a state where raw milk purchases are legal they are free to use and enjoy raw milk. However, once they enter into a state that has determined that raw milk is illegal, or regulated strictly, that state has the right to enforce their law. While the Plaintiff's are challenging the federal regulation against intrastate commerce of raw milk, the enforcement actions that have been taken against Plaintiff's have all been carried out on the state level. Plaintiffs claim that if the FDA truly believed that raw milk was inherently dangerous it would not have left enforcement of raw milk to a multitude of state regulation.¹³⁷ Plaintiff's claim this gap in FDA's logic, demonstrates that the only purpose of the pasteurization requirement is to stop raw milk from being distributed from state to state,

¹³⁴ Jones v. Helms, 452 U.S. 412, 219 (1981).

¹³⁵ Bach v. Pataki, 408 F.3d 75, 87 (2nd Cir. N.Y. 2005) (cert denied 126 S.Ct. 1341).

¹³⁶ See *Minnesota Senior Federation v. United States*, 273 F.3d 805, 807 (2001).

¹³⁷ See Plaintiff's Brief, *supra* note 120, at 37.

therefore restricting state travel.¹³⁸ While the right to travel liberty interest has been previously recognized by the Supreme Court, it is unlikely that a court will extend this interest to cover flagrant attempts to violate state law.

4. Liberty Interest-The Right to Raise Your Children and Eat the Foods Which you Choose.

In addition, the courts have recognized liberty interest in the educating and reading your children.¹³⁹ There have also been instances of the courts rejecting an absolute right to raise your children in a manner you see fit.¹⁴⁰ In regards to the right person right to eat foods of your choice, there is no recognized right of physical and bodily health. In their brief, Plaintiff's argue that it has never been illegal to consumer raw milk and that thousands of dairy farmers do it every year.¹⁴¹ In addition, the federal requirement of milk pasteurization is a fairly recent initiative and the United States has a social heritage connected with dairy farming and the consumption of raw milk.¹⁴²

However, this ignores the reality that federal regulations regarding food safety have been in place for over a hundred years. The first enacted federal food safety regulations were the Pure Foods and Drugs Act of 1906.¹⁴³ These regulations have only

¹³⁸ *Id.*

¹³⁹ *Pierce v. Society of Sisters*, 268 U.S. 510, 535 (1925), *see also Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

¹⁴⁰ *See Doe, supra* note 132, at 710; *see also Henne v. Wright*, 904 F.2d 1208, 1214 (8th Cir. 1990)(cert denied 111 S.Ct. 692 (1991) (upholding a restriction on choice of surname for child).

¹⁴¹ *See Plaintiff's Brief, supra* note 120, at 44.

¹⁴² *See Plaintiff's Brief, supra* note 120, at 44-45.

¹⁴³ P.L. 59-384, 34 Stat. 768 ("For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors and for regulating traffic therein, and for other purposes").

been expanded and extended since their enactment. On January of 2011, President Obama signed the Food Safety Modernization Act into law, substantially expanding food safety requirements with the mission of reducing the number of outbreaks due to food illnesses.¹⁴⁴

The largest problem with Plaintiff's argument is that the FDA has not taken any action, nor has any rule against the consumption of raw milk or raw milk products for adults or their children. Instead, the regulation focuses on the sale and distribution in interstate commerce of a product that the FDA has deemed "unsafe" to drink. By focusing the regulation on this interstate commerce tilt, the FDA has sought to avoid violating liberty interests of plaintiffs or any American citizens. Rather than taking milk out of the hands of Americans and their children, the pasteurization requirement simply dictates that persons can not sell the milk in interstate commerce.

Lastly, even if Plaintiffs are able to prove that a liberty interest has been violated, they will still have to weigh this against the governmental interest described in prong three of the *Mathews* test.¹⁴⁵ The history of substantial illnesses due to milk contamination laid the foundation for the FDA seeking to prevent another health crisis related to milk. It cannot be ignored that FDA went through a substantial rulemaking process involving years of testimony and medical evidence. Charged with determining the best way with protecting the public from food-borne illnesses related to milk, the FDA choose what they believes was the best course of action, mandatory

¹⁴⁴ P.L 111-353, available at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm>.

¹⁴⁵ See *Mathews*, *supra* note 129, at 355.

pasteurization.¹⁴⁶ Being that they are the agency delegated by Congress to protect the public health of American food, their decision will likely be deferred to by a court.

5. Challenge to the Pasteurization Regulation as an Arbitrary and Capricious Exercise of Power.

If Plaintiff's due process claim fails, their next avenue for challenging the Pasteurization Regulation is to claim that the FDA's decision was arbitrary and capricious. When a reviewing court is examining an agency's construction of a statute, it is guided by *Chevron*¹⁴⁷ deference. *Chevron* dictates that the court must first, "question whether Congress has directly spoken to the precise question at issue."¹⁴⁸ If Congress has not directly addressed the issue then the court must determine, "whether the agency's answer is based on a permissible construction of the statute."¹⁴⁹ As was stated earlier, FDA's ban on interstate sales of unpasteurized milk was promulgated under its authority to create regulation that prevent the introduction of communicable diseases¹⁵⁰ and its authority to promote public health by ensure foods are "safe, wholesome, sanitary and properly labeled."¹⁵¹ The Supreme Court has previously given the FDA a wide breadth to promulgate regulations to protect consumer health and welfare, especially in regards to food safety.¹⁵²

¹⁴⁶ See Pasteurization Rule, *supra* note 32, at 29513.

¹⁴⁸ *Chevron U.S.A. v. Natural Resources Defense Council* 467 U.S. 837, 842-843 (1984).

¹⁴⁹ *Id.* at 843.

¹⁵⁰ 42 USC 264(a).

¹⁵¹ 21 USC 393(b)(2).

¹⁵² See *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120, 133 (2000); see also, *United States v. Park*, 421 U.S. 658, 671 (1975) ("the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care").

As far as the first prong of the *Chevron* test, it can be argued that Congress specifically gave FDA the regulatory authority to promulgate regulations regarding food and food safety. A court will likely find that the FDA is well within its statutory limits to regulate milk and proper ways to ensure milk safety. However, if a reviewing court does find that the regulations fail *Chevron*'s first test, a reviewing court will likely hold that FDA has reasonably construed the statutes. FDA has promulgated hundreds of regulations regarding the treatment of food.

The consolidation of the dairy industry leads to the conclusion that American consumers will be receiving their milk from fewer farms and therefore milk will be more likely than ever to travel through interstate commerce. As the dairy industry changed the FDA decided that it was time to regulate the sale of milk and how it should be treated. Seeing pasteurization as the most efficient way to ensure milk safety and quality, the FDA spent 13 years gaining information in order to make a decision. *Chevron* dictates that a reviewing court decides that, "Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation."¹⁵³ Since a reviewing court will likely give deference to the FDA under *Chevron*, it is likely that Plaintiffs will fail in their suit against the FDA.

IV. Conclusion

In conclusion, the number of raw milk consumers will likely grow in number if current trends continue. With an increase in publicity and demand, raw milk producers and consumers can expect more enforcement actions against them from state regulators and the FDA. If advocates wish to have greater access to raw milk supply, they should

¹⁵³ See *Chevron*, *supra* note 148, at 843-844.

focus on lobbying their state legislatures. The Pasteurization Regulation was passed through the official rulemaking responsibility of the FDA and any challenge will likely fail due process and or de novo challenge. Challenging the FDA Pasteurization Regulation in federal district court is an ineffective use of raw milk advocates time and money. Because a court will likely side with the FDA, raw milk drinkers should look to encouraging their state legislatures for more positive regulation for raw milk producers. As is the case in New Jersey, supporters can make economic and health arguments to their state officials to allow for certified raw milk. While certification will not eliminate all illnesses, it will allow for farmers and consumer who choose this lifestyle to accomplish this without seeking illegal methods of acquiring raw milk. In addition, supporters should invest in further medical studies related to raw milk. Currently, most studies are based on evidence from the 1920's. If more states allow for raw milk sales, more data will be available for proponents who eventually wish to lobby FDA to change the Pasteurization Regulation.