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## Moo-nshine: Resistance to FDA Regulation of Raw Milk

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**Moo-nshine: Resistance to FDA Regulation of Raw Milk**

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## Abstract:

Although drinking unpasteurized or “raw” milk can cause bacterial infection, raw milk enjoys a passionate following among consumers and farmers. This paper explores FDA regulation of raw milk and focuses on the legal strategies used to fight its regulation such as labeling the milk as pet food. Effects of these strategies on state regulation are also considered, as are their policy implications.

## I. Introduction

People will break the law to get it. They’ll eat their pets’ food to taste it.<sup>1</sup> They’ll manage a farm to get their hands on it<sup>2</sup>. One enthusiastic lawbreaker has likened it to drinking “melted French vanilla ice cream”<sup>3</sup>. The federal government has been encouraging states to require the pasteurization of milk for more than 80 years,<sup>4</sup> but consumers not only still drink raw milk, they will pay up to twelve times as much for the sweet contraband as for pasteurized milk.<sup>5</sup>

This Paper explores FDA regulation of unpasteurized or “raw” milk, the strategies employed to defeat it,

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<sup>1</sup>See *infra* at Part III.A

<sup>2</sup>Katy McLaughlin. “Got Raw Milk? Not Unless You Own Your Own Cow; Farmers Offer Bovine Stakes To Bypass Health Rule; Wisconsin Sours on Plan.” Wall Street Journal: Sep 11, 2003. pg. A1. (describing consumers who became shareholders of a farm and participated in management solely for raw milk access).

<sup>3</sup>Id.

<sup>4</sup>Grade A Pasteurized Milk Ordinance (2003 Revision). Introductory Materials. *at* <http://www.cfsan.fda.gov/~ear/pmo03.html> (last visited April 24, 2005).

<sup>5</sup>McLaughlin at A1 (unpasteurized milk fetched up to \$12 a gallon at a time when pasteurized milk prices were \$.94).

and the implications of those strategies for the FDA and state regulators. Part II provides a brief overview of state and federal milk law and the health issues involved with raw milk. Part III explores the range of techniques currently and recently used to avoid FDA and state pasteurization requirements, and focuses on the most effective of these, the sale of raw milk as pet food. Part IV considers the policy implications of the avoidance tactics and tentatively recommends FDA inaction. Part V concludes.

## II. Background

FDA regulation of raw milk has emerged slowly and fitfully. In 1924, the FDA developed a model code for states to use in regulating milk, then called the Standard Milk Ordinance (now the “Pasteurized Milk Ordinance” or “PMO”), which bans raw milk and its products from being sold to consumers.<sup>6</sup>

The FDA took no action more stringent than providing this model pasteurization code to states for nearly 50 years. In 1973, the agency issued a regulation requiring pasteurization of all milk traveling in interstate commerce,<sup>7</sup> but modified that regulation to exempt “certified” raw milk a year later.<sup>8</sup> In the wake of findings that certified raw milk presented significant disease risk from bacteria such as *Campylobacter* and *Salmonella*, the FDA began to reconsider its position in the early 1980s.<sup>9</sup>

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<sup>6</sup>“List of Previous Editions of PHS/FDA Milk Ordinance.” Grade “A” Pasteurized Milk Ordinance 2001 Revision (May 15,2002) at <http://www.cfsan.fda.gov/~ear/pmo01.html> (last visited April 24, 2005); Grade “A” Pasteurized Milk Ordinance 2003 Revision Section 9. (“From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade “A” pasteurized, ultra-pasteurized, or aseptically processed milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments.”)

<sup>7</sup>38 Fed.Reg. 27924 (1973).

<sup>8</sup>39 Fed. Reg. 42351 (1974).

<sup>9</sup>*Public Citizen v. Heckler*, 602 F. Supp. 611, 612 (D.D.C. 1985).

Developments in state law have moved in tandem with the FDA's gradual shift toward regulation. Thirty states permitted raw milk sales to consumers in 1985, and only 22 states do today.<sup>10</sup> Several states have adopted the PMO without varying from or modifying its provisions banning raw milk sales.<sup>11</sup>

California, where most raw milk has historically been produced,<sup>12</sup> has maintained its own standards for raw milk production since its "Milk and Milk Products Act of 1947."<sup>13</sup> The Milk and Milk Products Act creates three types of classifications for raw milk: certified, guaranteed and Grade A raw milk. Guaranteed raw milk has the strictest requirements – monthly inspection for all cows and goats, produced using containers with a pouring lip protected from contamination, and containing no more than 10,000 bacteria per milliliter, and sold within 30 hours of production. The more lenient Grade A standards, which drop the pouring lip and sale within 30 hours requirements and increase the acceptable bacteria count to 15,000 per milliliter. Certified raw milk depends upon nonexistent county milk commissions to set standards.<sup>14</sup>

No guaranteed or certified milk is available in California today<sup>15</sup>, but even California's least restrictive standard is better than most – only two other states formally require bacteria counts of raw milk be taken.<sup>16</sup>

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<sup>10</sup>See 602 F.Supp. at 612 (from 1974 to 1982, many states banned raw milk, bringing the total to 20 by 1985; as the compilation of state laws at <http://www.realmilk.com/milk-laws-1.html> demonstrates, 28 states currently ban raw milk sales (last visited April 24, 2005). Movement continues on the legislative front, with Virginia banning sales of raw milk cheese and butter in January. Marguerite Higgins. "State Bans Unpasteurized Milk Products." *Washington Times* January 26, 2005. available at <http://washingtontimes.com/business/20050125-092924-9352r.htm> (last visited April 24, 2005).

<sup>11</sup>See, e.g. Alabama Administrative Code 420-3-16; 11 Hawaii Administrative Rules 15:46; 15 Indiana Code 2.1:23-8.; 5 Iowa Statutes 192.103; 32 Montana Administrative Rules 8.102; 4 North Dakota Statutes 4-30-36.4; Tennessee Rules and Regulations 80-3-2.

<sup>12</sup>602 F.Supp. 611, *supra* at note 9.

<sup>13</sup>See California Food and Agriculture Code Division 15 "Milk and Milk Products Act of 1947." Sections 35787 (dividing "market milk" into acceptable grades); 35891(listing requirements for Grade A milk); *see also* 32903 (requiring tuberculin tests for cows used in raw milk production).

<sup>14</sup>*Id.*

<sup>15</sup>"What's happening with Real Milk?" at <http://www.realmilk.com/happening.html> (last visited April 24, 2005); "Organic Pastures Dairy Company – Nutrition" at <http://www.organicpastures.com/nutrition/> (last visited April 24, 2005) (listing Grade A milk as the only kind available).

<sup>16</sup>22 Connecticut Statutes 133-113 permits a bacteria count of 30,000 per milliliter, and 15 Washington Revised Code 36.012 permits only 20,000 per milliliter. Both of these statutes regulate the number of coliform bacteria that may be present in milk, however, unlike California.

In 1986, the nonprofit organization Public Citizen successfully sued to force FDA to enact a regulation barring the sale in interstate commerce of all unpasteurized milk, on the grounds that it had unreasonably delayed in doing so after comments received during a Department of Health and Human Services hearing showed milk to be significantly safer when pasteurized than when left unpasteurized.<sup>17</sup> The Secretary of HHS had refused to enact an interstate ban on the grounds that interstate sale of raw milk was a minor problem, but the court in *Public Citizen v. Heckler* held that this was not an acceptable reason for failing to regulate; the risk to an individual consuming milk produced in another state could be high, and that individual would have no recourse to the state legislature under whose watch the milk was produced.<sup>18</sup>

In the 29 years since *Public Citizen v. Heckler*, bacteria in raw milk have continued to cause health problems. There have been many recent disease outbreaks associated with raw milk. In 2002 and 2003, for example, 62 individuals, mostly children, contracted Salmonella as a result of inadequate hygiene at a dairy.<sup>19</sup> A 2001 Wisconsin dairy selling raw milk caused Campylobacter infection in 75 customers.<sup>20</sup> Between 1972 and 2000, the CDC is aware of 58 outbreaks associated with raw milk, only 29% of which were caused by a strain of the Salmonella bacterium.<sup>21</sup>

Despite California's independent regulatory standards, its raw milk presents significant health risks. Alta-

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<sup>17</sup>Public Citizen v. Heckler, 602 F. Supp. 611 (D.D.C. 1985) (ordering FDA to issue proposed rule reflecting action on Public Citizen's petition to regulate raw milk); Public Citizen v. Heckler, 653 F. Supp. 1229 (D.D.C. 1986) (ordering FDA to promulgate regulations banning interstate sales of raw milk, but not intrastate sales).

<sup>18</sup>653 F.Supp. at 1240-1241.

<sup>19</sup>Centers for Disease Control. "Multistate Outbreak of *Salmonella* Serotype Tymphimurium Infections Associated with Drinking Unpasteurized Milk – Illinois, Indiana, Ohio, and Tennessee, 2002-2003." Morbidity and Mortality Weekly Report 52(26) p. 613-615 (July 4, 2003). available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5226a3.htm> (last visited April 24, 2005).

<sup>20</sup>Centers for Disease Control. "Outbreak of *Campylobacter jejuni* Infections Associated with Drinking Unpasteurized Milk Procured through a Cow-Leasing Program – Wisconsin 2001." Morbidity and Mortality Weekly Report 51(25) p. 548-49 (June 28, 2002). available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5226a3.htm> (last visited April 24, 2005).

<sup>21</sup>Centers for Disease Control. "Multistate Outbreak of *Salmonella* Serotype Tymphimurium Infections Associated with Drinking Unpasteurized Milk – Illinois, Indiana, Ohio, and Tennessee, 2002-2003." Morbidity and Mortality Weekly Report 52(26) p. 613-615 (July 4, 2003). available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5226a3.htm> (last visited April 24, 2005).

Dena Certified Dairy, in 1992 the supplier of 90% of California's raw milk, was found in *Consumers Union v. Alta-Dena Certified Dairy* to have caused "numerous" illnesses via raw milk, including the Salmonella-induced heart aneurysm of a woman who drank Alta-Dena's product.<sup>22</sup> The milk of cows infected with Salmonella dublin can contain that pathogen regardless of the health measures taken by the dairy company; even Alta Dena's own experts testified that its milk was more dangerous than pasteurized milk.<sup>23</sup> As a result of these facts, the court enjoined Alta-Dena from continuing to make false and misleading claims about the safety and health benefits of raw milk and required it to place a warning label on its raw milk products.<sup>24</sup> Alta Dena no longer sells raw milk.<sup>25</sup>

The Centers for Disease Control estimated in 1984 that drinking raw milk instead of pasteurized milk in California increased one's risk of contracting Salmonella dublin from that milk by a multiple of 158.<sup>26</sup> One's odds in 1983 of contracting that particular strain from drinking raw milk were about 1 in 2,000 if one drank a pint of raw milk every day, compared to 1 in 300,000 for a daily pint of pasteurized milk.<sup>27</sup>

Technology has improved since 1992, however; a batch of raw milk can now be tested for the presence of Salmonella, the bacterium identified as the primary health concern in *Consumers Union*, in just 24 hours.<sup>28</sup>

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<sup>22</sup>Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy, 4 Cal.App.4th 963, 6 Cal.Rptr.2d 193, 195 (1<sup>st</sup> Dist.1992).

<sup>23</sup>Id. at 197.

<sup>24</sup>Id. The court-ordered warning label stated:

Warning: This Milk May Contain Dangerous Bacteria. Those Facing the Highest Risk of Disease or Death Include Babies, Pregnant Women, the Elderly, Alcoholics, Those With Cancer, AIDS or Reduced Immunity and Those Taking Cortisone, Antibiotics or Antacids. Questions Regarding the Use of Raw Certified Milk Should Be Directed to Your Physician.

<sup>25</sup>"Alta Dena Milk Products" at <http://www.altadenadairy.com/addProductsMilkCream.asp> (last visited April 24, 2005) (list does not include raw milk).

<sup>26</sup>Centers for Disease Control. "Salmonella Dublin and Raw Milk Consumption – California." Morbidity and Mortality Weekly Report 33(14) p. 196-198 (April 13, 1984). available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000318.htm> (last visited April 24, 2005).

<sup>27</sup>Id.

<sup>28</sup>Malorny B, Paccassoni E, Fach P, Bunge C, Martin A, Helmuth R. "Diagnostic real-time PCR for detection of Salmonella in food." Applied Environmental Microbiology. 70(12) (December 2004):7046-52. (describing a completely accurate polymerase chain reaction test by which food including raw milk can be tested for all Salmonella strains in 24 hours).

Organic Pastures Dairy<sup>29</sup> touts bacteria counts from the raw milk it sells as being beneath 15,000 per milliliter, the same standard that Alta Dena had to meet.<sup>30</sup> Organic Pastures Dairy also claims to test regularly for Listeria, E.Coli, and Salmonella, however,<sup>31</sup> which could drive down risk beneath the levels identified by the Centers for Disease Control.

Raw milk offers no demonstrable health benefits to offset the risks it creates. The *Consumers Union* court found after an extensive trial that Alta-Dena Dairy's claims that raw milk contained more calcium and other vitamins were false.<sup>32</sup> When the FDA banned raw milk from interstate commerce after many years of inquiry in 1987, it concluded that "[t]he theoretical benefits of raw milk have never withstood scientific scrutiny."<sup>33</sup> Nothing has emerged since to seriously challenge that conclusion: of 960 articles in medical journals on raw milk published since 1950, none show raw milk to offer any health benefit over pasteurized milk.<sup>34</sup>

Raw milk's largest benefit is aesthetic: many consumers prefer its taste to that of pasteurized milk. The court in *Public Citizen v. Heckler* noted that raw milk proponents testified that it tasted better than pasteurized milk.<sup>35</sup> A study of Irish farmers exploring reasons why they continued to drink raw milk despite health risks found that they felt raw milk to be higher quality than pasteurized milk.<sup>36</sup> California consumers of raw milk

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<sup>29</sup>Organic Pastures Dairy is by no means the largest dairy in the world, as the Consumers Union court suggested Alta-Dena to be, but it is large enough to have claimed 1-877-RAW-MILK as its telephone number. Id.; "Organic Pastures Dairy Company" at <http://www.organicpastures.com> (last visited April 24, 2005).

<sup>30</sup>See Organic Pastures Dairy Company Lab Tests at <http://www.organicpastures.com/labtests/> (touting scores beneath the California Department of Food and Agriculture raw milk standards of 15,000 bacteria per mL) (last visited April 24, 2005).

<sup>31</sup>"Organic Pastures Dairy Company – FAQ" at <http://www.organicpastures.com/faq/>

<sup>32</sup>4 Cal. App. 4<sup>th</sup> at 970.

<sup>33</sup>Final Rule. "Milk, Lowfat Milk, and Skim Milk, Pasteurization Requirements for Fluid Milk Products for Consumer Use." 52 Federal Register 29509 (August 10, 1987).

<sup>34</sup>Based on a search for "raw milk" at <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed>. The closest any study comes to showing raw milk to be better than pasteurized milk was a study conducted in Turkey that found that some strains of Listeria were more common in Turkish pasteurized milk than Turkish raw milk, although the pasteurized milk was less likely to contain Listeria overall. Ahrabi SS, Erguven S, Gunalp A. "Detection of Listeria in raw and pasteurized milk." *Central European Journal of Public Health*. 6(3), August 1998, p. 254-5. Potential inadequacy of Turkish pasteurization processes does not have much relevance for milk policy in the U.S., however.

<sup>35</sup>653 F. Supp. 1229, 1234 (D.D.C. 1986)

<sup>36</sup>The farmers also drank raw milk out of tradition. Hegarty H, O'Sullivan MB, Buckley J, Foley-Nolan C. "Continued raw milk consumption on farms: why?" *Communicable Disease and Public Health*. 5(2) (June 2002) 151-6.



also report that they prefer its taste.<sup>37</sup>

Another appeal of raw milk to consumers may be its association with organic food. Farms that sell raw milk also promote “grass fed beef,”<sup>38</sup> eggs from “free ranging, pastured hens,”<sup>39</sup> field questions about whether their milk is organic,<sup>40</sup> and, in the case of Organic Pastures Dairy, choose a name that capitalizes on the positive image of organic food.<sup>41</sup> A video on Organic Pastures Dairy’s website touts their raw milk and other foods as “a new probiotic, biodiverse, healthier way of eating and living for you and your family”.<sup>42</sup> Claravale Farms’ raw milk is sold in California at the organic grocery chain Whole Foods.<sup>43</sup> Tapping into a subculture whose members trust “natural” food more than processed food is a useful technique for marketing raw milk.

Raw milk producers and consumers have not sat idly by while the FDA and state governments banned their beverage, and have developed several strategies for fighting regulation. Part III takes up these strategies.

### III. Legal Strategies for Circumventing Raw Milk Laws

#### A. Selling Raw Milk as Pet Food

##### 1. Overview of Strategy

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<sup>37</sup>Headrick ML, Badgaleh T, Klontz KC, Werner SB. “Profile of raw milk consumers in California.” Public Health Reports 112:418 (1997).

<sup>38</sup>“Peaceful Pastures – Beef” at <http://peacefulpastures.com/beef.htm> (last visited April 24, 2005). Peaceful Pastures sells raw milk as pet food to circumvent FDA restrictions; see *infra* Part III.A.

<sup>39</sup>“Peaceful Pastures – Eggs” at <http://peacefulpastures.com/eggs.htm> (last visited April 24, 2005).

<sup>40</sup>“Claravale Farm.” at <http://claravalefarm.com/FAQ.htm> (last visited April 24, 2005)

<sup>41</sup>“Organic Pastures Dairy Company” at [www.organicpastures.com](http://www.organicpastures.com) (last visited April 24, 2005).

<sup>42</sup>Id. at “New OPDC Video – Click Here!”

<sup>43</sup>“Claravale Farm.” at <http://claravalefarm.com/location.htm> (last visited April 24, 2005).

One creative and ultimately successful attempt to circumvent the FDA ban on interstate shipment is to classify and market raw milk and milk products as pet food.<sup>44</sup> Peaceful Pets, a farm in bucolic Hickman, Tennessee, sell raw milk, cream, butter and cheese on their website:

The dairy products are from grass fed dairy animals here at Peaceful Pets. We use milk, milk products and milk by products [sic] as a regular part of our animals' raw diet. The dairy products are obviously useful in rearing baby animals especially those who are orphaned, but they can also play a key role in returning sick or convalescing animals to better health.

[Peaceful Pets dairy products are offered and intended solely for animal consumption [sic] These products are not approved, inspected, regulated or legal for human consumption. Due to significant legal and liability issues, we cannot and will not answer questions regarding human consumption of these or any other raw milk products-please don't ask.]

It seems unlikely that many pet owners would bother going to the relatively high expense – \$63 to send 5 pounds of Peaceful Pets' milk and cheese to Boston, for example<sup>45</sup> – of obtaining unpasteurized dairy products for their pets. The bacteria in raw milk are unsafe for animals as well as for humans, and veterinarians therefore caution against serving unpasteurized food to pets.<sup>46</sup> One imagines the statement that “[t]hese products are not approved, inspected, regulated or legal for human consumption” being made with a wink and a nod, since the adjective “safe” is omitted.

Peaceful Pets may well intend their raw milk products to be consumed only by pets. The non-dairy products

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<sup>44</sup>See “Peaceful Pastures Dairy Products.” *available at* <http://peacefulpastures.com/petfood/dairy.htm> (last visited April 24, 2005)

<sup>45</sup>Id.

<sup>46</sup>“Feeding Pets in the 90s” *at* <http://www.akcchf.org/research/articles/whitepapers/feedpets90s.pdf> (last visited April 24, 2005).

sold are mostly meat intended for human consumption, and while consumers who eat grain-fed lamb may be the same consumers who drink raw milk, they might also be the type of consumers who feed raw milk to their pets. But the farmers have clearly thought a lot about what food pets should be eating,<sup>47</sup> and the Peaceful Pets logo prominently features a dog and cat chowing down. The president of Tennesseans for Raw Milk has asserted, in reference to the Peaceful Pets products, that “[t]here’s nothing illegal about eating your pet’s food,” but the owners only express regret that they cannot sell raw milk for human consumption.<sup>48</sup>

At least two other companies will ship raw milk for pet consumption across state lines. Golden Fleece Dairy touts its low-temperature “VAT pasteurization method” for the milk it sells for human consumption, but also sells raw milk “for pet food only – not for human consumption.”<sup>49</sup> Organic Pastures Dairy will ship raw milk to California for human consumption, but ships that same product out of state “labeled and intended” for use as pet food.<sup>50</sup>

Of these three raw milk producers, two might well intend their milk to be consumed only by pets. Organic Pastures’ strategy of selling the same raw milk within California as around the country, with the sole difference that milk sold out of state is labeled for pet purposes only, is more enticing. The prospective

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<sup>47</sup>As one page on the site notes, “Pet Lovers are in a different group than pet owners; we want what is truly best for our kind companions. Commitment, proper veterinary care, and the best food that is truly what nature intended.

What we feed our pets and why.

We feed our animals a BARF diet of raw meat, raw eggs and raw dairy (milk, yogurt and cheese). We do not supplement with any grains or vegetables.

This does go against some of the mainstream BARF thinking, but our reasoning is this: we have never seen any of our dogs go dig up a turnip and eat it. The diet of wild dogs would include vegetables and dairy ONLY as undigested stomach contents of the animals hunted. The chicken gizzards we sell and feed contain undigested grass and some grains.”

at <http://peacefulpastures.com/petfood/our-pets.htm> (last visited April 24, 2005).

<sup>48</sup>Mitchell Kline. “Advocates of raw milk form dairy underground.” *The Tennessean* Dec. 28, 2004 available at <http://www.tennessean.com/local/archives/04/12/63400735.shtml> (last visited April 24, 2005).

<sup>49</sup>“Golden Fleece Dairy” at <http://www.goldenfleece.net/dairy.htm>; “Golden Fleece Products” at <http://www.goldenfleece.net/products.htm> (last visited April 24, 2005).

<sup>50</sup>“Organic Pastures Dairy Company – Order Now!” at <http://www.organicpastures.com/ordernow/> (“In compliance with FDA regulations and CFR 1240.61, OPDC does not take orders or ship any raw dairy products for human consumption outside of the State of California. All out of state product sales are labeled and intended for pet food consumption only.”)

out-of-state consumer who intends to drink the “pet food” milk herself knows that she is getting milk that meets California’s raw milk standards, and knows further that Organic Pastures may face liability or some regulatory response if it produces unsafe milk. It is thus particularly effective.

## 2. FDA Regulation of the Pet Food Strategy

Marketing raw milk as pet food skirts FDA restrictions on interstate raw milk sales. The Federal Food, Drug, and Cosmetic Act defines “food” as “articles used for food or drink for man or other animals,” extending FDA’s authority to cover pet foods.<sup>51</sup> FDA regulation of animal feed imposes no pasteurization requirements<sup>52</sup>, however. The regulation requiring the pasteurization of milk and milk products in interstate commerce is entitled “Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.”<sup>53</sup> The text of this regulation, 21 C.F.R. 1240.61, requires pasteurization of milk and its products “delivered into interstate commerce . . . in final package form for direct human consumption.” The regulation is on its face inapplicable to pet food.<sup>54</sup>

The notices of the pasteurization regulations printed in the Federal Register further demonstrate that FDA did not intend to regulate animal consumption of raw milk. The Federal Register notice announces “Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce” and “Requirement for

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<sup>51</sup>Federal Food, Drug and Cosmetic Act. 21 U.S. Code 501, Sec. 201

<sup>52</sup>See 21 C.F.R §§500-599.

<sup>53</sup>21 CFR § 1240.61. This regulation implements the Public Health Service Act, which authorizes such regulations as are necessary to “prevent the introduction, transmission or spread of communicable diseases.” 42 U.S.C. § 264(a). See also 21 C.F.R. 131.110 ( “Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized”).

<sup>54</sup>Id.

Fluid Milk Products for Consumer Use.”<sup>55</sup> The text of the notice refers to milk products “sold for human consumption.”<sup>56</sup>

Selling milk products intended for pets (even those which might be, unbeknownst to the seller, used by humans) cannot be challenged under these regulations, and thus the practices of Golden Fleece and Peaceful Pets are legal.<sup>57</sup>

Organic Pastures Dairy’s obviously insincere approach is not so clearly legal, however. Organic Pastures Dairy sells its milk in the same form both in-state and out-of-state; the out-of state version contains the same nutritional information (and attendant strong implication that it is safe for humans) and only differs in the hastily stuck-on “for pets consumption” label.<sup>58</sup>

The best argument for the illegality of Organic Pastures Dairy’s approach is that their raw milk is actually intended for human consumption, despite labeling to the contrary. While this may be true, it would require a huge commitment of FDA resources to ascertain the intent of every distributor of raw milk as pet food. FDA will probably not be able to rely on state determinations of “intent” to defeat practices of those like Organic Pastures Dairy: Oregon’s Department of Agriculture was satisfied with Organic Pastures Dairy’s “intent” after the dairy put a label on their milk that stated “for pet consumption.”<sup>59</sup> An FDA challenge might also be ineffective because it would serve as a signal to consumers that a disclaimer that raw milk

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<sup>55</sup>52 Federal Register 29509 (August 10, 1987).

<sup>56</sup>Id.

<sup>57</sup>See *supra* at notes 47 and 49 and accompanying text for descriptions of these practices.

<sup>58</sup>April Streeter. “Organic Pastures butters up Oregon.” *Sustainable Industries Journal Northwest* March 1, 2005 (reporting that Organic Pastures was able to sell its products in Oregon after applying a “for pet consumption only” sticker to raw milk jugs.) available at <http://www.sijournal.com/foodandfarms/1347327.html> (last visited April 24, 2005).

<sup>59</sup>Id.

is only for pet use is a mere fig leaf that does not reflect the actual intended use of the product. Such a challenge could embolden consumers to drink raw milk despite a “for pets only” label.

Because the FDA cannot plausibly argue that their milk pasteurization regulations apply to pet food<sup>60</sup>, Organic Pastures Dairy’s approach will be safe from FDA action unless and until the agency promulgates regulations that ban raw milk sales for animal consumption in interstate commerce.

### 3. State Regulation of Pet Food Strategy

The pet food strategy just described, which consists of classifying raw milk as pet food and selling it in

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<sup>60</sup>The only possible argument on this point is that, because Organic Pastures’ products are sold for human consumption in California, and *in that same form* elsewhere, they are required to be pasteurized under 21 C.F.R. 1240.61. The argument would assert that FDA did not consider a situation in which raw milk was packaged for human use, but also sold in that same package form for animal use, and thus failed to exclude that situation from the regulation’s text. The argument is quite weak, however.

The regulation mandates pasteurization for “any milk or milk product in final package form for direct human consumption.” An FDA argument that Organic Pastures’ behavior was covered by the statute would read the phrase “for direct human consumption” to clarify what counts as “final package form.” A milk product is regulated if that product is in its final package form. How does one know when a product reaches final package form? One knows because the product is in the form where a consumer will drink it (a human will consume it). The milk will not have to be piped into bottles or cartons.

The better interpretation of the language reads the phrase “final package form for direct human consumption” to create two conditions for milk to fall under the regulation: milk must (1) be in final package form, but it must (2) also be intended for human consumption. If it’s in final package form for pet food, then the regulation doesn’t apply. This interpretation is consistent with the announced intent of the FDA to regulate only the human consumption of raw milk.

The language in the other pasteurization provision of the C.F.R. announced the same day could provide some support to the first, weaker interpretation. Final Rule. “Milk, Lowfat Milk, and Skim Milk, Pasteurization Requirements for Fluid Milk Products for Consumer Use.” 52 Federal Register 29509 (August 10, 1987). That rule mandates pasteurization for “[m]ilk that is in final package form for beverage use.” 21 C.F.R. 131.110. This suggests that the text of 21 C.F.R. 1240.61, which covers both milk *and milk products* had to vary from this language because cheese is not sold in beverage form.

The Federal Register notice announcing the final rule codified in 21 C.F.R. 1240.61 states that pasteurization is not required where raw milk is sent across state lines to be pasteurized. 52 Federal Register 29509 (August 10, 1987). This could suggest that the “for direct human consumption” language is not inserted to distinguish it from milk “for animal consumption,” but to identify the state in which raw milk is shipped to processing plants for pasteurization. The word “direct” is also meaningless if the clause is read to permit consumption by animals.

Under this view the regulation would still not apply to almost all sales for animal consumption because most milk sold for animal use would not be sold in the same final package form as raw milk sold to humans. At best this view would argue that the regulation should be interpreted so as to have been erroneously drafted not to apply to Organic Pastures’ situation.

A victory on this point would not even mean very much. Organic Pastures could argue in response that the inclusion of a “pet food only” label changes the final package form significantly, such that the “pet food only” carton sold in Oregon is not in the same final package form as the label-free product sold in California. Or it could just modify the packaging for the pet food/out-of-state milk until it was distinct from the packaging of in-state milk. Even completely distinct pet food packaging that gave no impression the product was safe for humans would not dent internet sales, since the Organic Pastures website makes clear that the in-state and out-of-state milk have the same source and composition.

interstate commerce, is thus safe under current FDA regulations. Defeating the FDA is itself very useful. Suppose there were no FDA regulation barring interstate commerce in milk – then Organic Pastures Dairy could set up shop in California and ship raw milk to every state that allowed such shipment.<sup>61</sup> The pet food strategy’s effects on state law make it even better than a total absence of FDA regulation, however. The strategy can significantly interfere with state efforts to bar raw milk, even were states inclined to enforce their raw milk statutes against out-of-state Internet raw milk sales.<sup>62</sup>

The “pet food” strategy avoids state raw milk regulation in three ways. First, it forces some states to amend their raw milk statutes to specifically bar the use of raw milk as pet food if those states wish to prevent Internet raw milk pet food sales. Some states have blanket raw milk bans that would conflict with FDA regulations if they were read to apply to raw milk in interstate commerce – suppose they require pasteurization of all raw milk products, for example, without making an exception for cheese aged 60 days.<sup>63</sup> Those statutes are either unconstitutional or, if constitutional, may only be applied to intrastate sales (and not to mail-order sales from out-of-state). A state that has enacted a separate provision regulating the sale of raw milk as pet food may bar out-of-state mail-order sales of pet food, but states that rely on a single law for all raw milk sales cannot apply that law in interstate commerce when doing so would conflict with FDA regulations.

Second, states that rely on strict licensing and inspection requirements in order to deter sales of raw milk may not be able to enforce them against out-of-state raw milk producers. Those producers would only have

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<sup>61</sup>Without any FDA regulation of interstate commerce of raw milk, there would be little doubt under the Commerce Clause about the ability of states to use raw milk laws to shield themselves against out-of-state raw milk shipments to consumers. *See* analysis *infra* at notes 66-67.

<sup>62</sup>Note that Oregon’s imposition of a labeling requirement for Organic Pastures Dairy, *supra* at note 58, dealt with supermarket sales rather than those made directly to the consumer.

<sup>63</sup>21 CFR 1250.26 permits the interstate shipment of cheese after it has aged for 60 days.

to comply with the inspection laws of the state in which they operate, not all the states to which they send milk.

Third, because more states ban raw milk for human than for animal consumption, the pet food technique increases the number of states in which raw milk can be sold. It dodges both FDA and state bans against raw milk sales at once.

The following example illustrates the first advantage, that conflicts between FDA regulations and state law can require states to amend their statutes before they may target Internet sales of raw milk as pet food. Suppose Organic Pastures Dairy ships raw milk to a customer in Iowa labeled for animal consumption. Iowa is one of the states that has adopted the Pasteurized Milk Ordinance without varying it.<sup>64</sup> Iowa's code provides that "[o]nly grade 'A' pasteurized milk and milk products shall be sold to the final consumer, or to restaurants, soda fountains, grocery stores, or similar establishments."<sup>65</sup> This statute does not distinguish between sales of milk for human and for animal consumption, and could be applied to both types of sale.<sup>66</sup>

If Iowa's raw milk statute were read to apply to milk shipped into Iowa from other states, it would not be constitutional because it lacks an exception for unpasteurized cheese aged 60 days or more. Where Congress through the FDA has acted to regulate an area of interstate commerce under the U.S. Constitution's Commerce Clause, state laws must yield to that regulation<sup>67</sup>; even absent federal action the ability of states

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<sup>64</sup>See *supra* at notes 6 and 11.

<sup>65</sup>5 Iowa Statutes 192.103.

<sup>66</sup>One should not conclude that the phrase "sold to the final consumer" excludes pet food, because a human will purchase the product and that human's pet will be the "final consumer" in that it will physically consume the food. The "final consumer" wording in the statute only makes sense to distinguish direct-to-consumer sales from sales to retailers. Further, this reading would have absurd consequences – permitting sales of raw milk to parents who will give it to their children, or those who promise to give it to their friends instead of drinking it themselves.

<sup>67</sup>The Constitution grants Congress the exclusive power "to regulate Commerce with foreign Nations, and among the several States." U.S. Const. Art. I, § 8, cl.3. Thus where Congress enacts a statute regulating interstate commerce, the states must yield to it under the Supremacy Clause; even where Congress has not acted, however, the "dormant commerce clause" acts as a



to regulate interstate commerce is limited severely.<sup>68</sup> A state regulation barring the shipment of raw milk cheese aged 60 days would not be constitutional if applied to interstate commerce because it would conflict with FDA regulations.<sup>69</sup>

Federal courts interpreting state laws that would be unconstitutional if applied to interstate commerce, but fine if applied to intrastate commerce, have read the state laws to be constitutional and intrastate in scope.<sup>70</sup> Their rationale is that an ambiguous statute should not be read in such a way as to render it unconstitutional.<sup>71</sup> A court would thus be likely to interpret a statute like Iowa's to apply only to intrastate commerce.<sup>72</sup>

If a state were to enact a distinct provision prohibiting the sale of raw milk as pet food<sup>73</sup>, that state could prevent raw milk from being shipped to its citizens from a different state. FDA has elected to defer to the states on regulation of animal food.<sup>74</sup> Because a state ban on raw milk sales to animals would be motivated

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default rule to prevent states from regulating interstate commerce where Congress has remained silent. *See, e.g. Oregon Waste Sys., Inc. v. Dep't of Env'tl Quality*, 511 U.S. 93, 98, (1994) (explaining this point of law).

<sup>68</sup>*Pike v. Bruce Church*, 397 U.S. 137 (1970) states the rule that under a dormant Commerce Clause analysis a state's interest in enforcing a statute is to be balanced against the burden that statute places on interstate commerce.

<sup>69</sup>21 C.F.R. 1250.26.

<sup>70</sup>*See National Pharms. Inc. v. De Melecio*, 51 F.Supp. 2d. 45, 59-60 (D.P.R. 1999), *aff'd* 221 F.3d. 235 (1<sup>st</sup>. Cir. 2000) (reading a Puerto Rico statute requiring the licensing – including inspection – of all pharmacies serving Puerto Rico customers by the Puerto Rico Secretary of Health to apply only to pharmacies physically located in Puerto Rico and not to a New Jersey mail-order pharmacy, where the Puerto Rico Supreme Court had recognized that a state can only exercise jurisdiction over persons within its own territory, and where to interpret the statute to apply to the New Jersey pharmacy would violate the dormant Commerce Clause). The Court of Appeals emphasized that because the court construed the Puerto Rico statute to apply only to Puerto Rico, it did not reach the constitutionality of the statute if applied differently, although it referred to the statute so applied as “of questionable constitutionality.” 221 F.3d. at 242.; *See also* *Ctr. for Disease Det., LLC v. Rullan*, 288 F.Supp.2d. 136 (D.P.R. 2003) (applying *National Pharms.* and reading a statute requiring licensing and inspection of laboratories not to apply to work done by an out of state laboratory in connection with a contract with the Puerto Rico Department of Health).

<sup>71</sup>*Id.*

<sup>72</sup>Statutes which do not conflict with FDA regulations might be interpreted to apply to interstate commerce, given the safety rationale for such statutes. *See Hillsborough County, infra* at note 75.

<sup>73</sup>So far, no state has done this. “An Overview of U.S. State Milk Laws.” at <http://www.realmilk.com/milk-laws-1.html> (last visited April 24, 2005). Michigan has enacted a separate provision specifying that “dairy plant byproducts used for animal feeding purposes shall be pasteurized,” but this does not apply to raw milk from a farm. Michigan Compiled Laws 288.538 Sec. 68(3).

<sup>74</sup>*See* “Standards for Animal Food and Food Additives in Standardized Animal Food.” 64 Federal Register 4293 (January 28, 1999) (announcing final rule removing procedural regulations for establishing animal food standards).

by the health and safety of animals rather than a desire to insulate in-state producers from competition, states can constitutionally bar the sale of raw milk as pet food<sup>75</sup> and prosecute raw milk feed sellers who ship to consumers via Internet sales.<sup>76</sup>

States that have banned raw milk sales by enacting the PMO or a similar statute have restricted themselves to the regulation of intrastate sales of raw milk and its products because the PMO is inconsistent with FDA regulation of interstate commerce in raw milk. Their only recourse against dairies such as Organic Pastures Dairy or Golden Fleece Dairy, or any other dairy that operates in a raw-milk-friendly state and ships raw milk into a state that has adopted the PMO, is to enact a statute specifically targeted at such raw milk pet food sales.

The second obstacle the pet food strategy poses to state attempts to regulate raw milk is the possibility that the dormant commerce clause prevents licensing and inspection requirements from being imposed on out-of-state producers. Where a state's licensing requirements for raw milk producers affect the equipment or production methods an out of state dairy may use, they are probably unconstitutional, although general registration requirements for pet food producers are valid.

In the recent cases *Centers for Disease Detention v. Rullan* and *National Pharmaceuticals v. De Melecio*, the courts refused to read licensing requirements to apply to out of state producers because to do so would render the requirements unconstitutional.<sup>77</sup> The Puerto Rico laws required inspection of out-of-state facilities.

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<sup>75</sup>See *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985) (stating that an FDA statement is dispositive of intent to preempt state law unless inconsistent with clearly expressed Congressional intent (citing *Chevron U.S.A. v. NRDC, Inc.*, 467 U.S. 837, 842-45 (1984); in such a case, deference to state regulation of health and safety matters justified additional requirements for blood donors against a Commerce Clause challenge). See also *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d. 200 (2<sup>nd</sup> Cir. 2003) (where a statute discriminates against interstate commerce in its face or on its effect, the state's justification for a rule is subjected to strict scrutiny).

<sup>76</sup>See 320 F.3d. at 219 (finding that while a state cannot prosecute the United States Postal Service under a law barring direct cigarette shipment to consumers for delivering the cigarettes, it can prosecute the out-of-state entity that shipped the product using the Postal Service.)

<sup>77</sup>See *National Pharms. Inc. v. DeMelecio, and Ctr. for Disease Det., LLC v. Rullan*, *supra* at note 70. These cases suggest

<sup>78</sup> This kind of requirement is an unconstitutional extension of a state’s jurisdiction beyond its boundaries because requiring a New Jersey company to alter its New Jersey production facilities as a condition for doing business in Puerto Rico has effects broader than restricting entry into Puerto Rico’s market. The New Jersey factory may also ship to other states like New York, and to require that factory to meet Puerto Rico standards is to impermissibly regulate beyond the authority of Puerto Rico.<sup>79</sup> If a state has sufficient justification, however, states may place incidental burdens on interstate commerce that treat in-state and out-of-state companies alike.<sup>80</sup>

Thus California’s requirement that cows producing raw milk be inspected every two months<sup>81</sup> would be unconstitutional if imposed on raw milk pet food producers outside the state. If California consumers ordered milk from Peaceful Pets’ farm in Tennessee, for example, California would not as a result have authority to inspect the Tennessee facilities. Its inspection requirements would be interpreted to apply only sales of raw milk within California. Similar requirements in other states would also have to be interpreted to apply only to intrastate sales or be struck down.<sup>82</sup> Less restrictive registration requirements, however, such as some states’ requirement that all pet food distributors register and pay a \$50 fee before distributing pet food<sup>83</sup> would be acceptable.

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that licensing requirements are governed by a line of cases that bar one state’s attempt to regulate the prices charged by a distributor in a different state under the Commerce Clause. *See, e.g. K-S Pharmacies v. American Home Products*, 962 F.2d 728 (7th Cir. 1992) (reading a Wisconsin statute so as to avoid an unconstitutional construction – that the statute required pharmacies to charge the same prices in other states that they did in Wisconsin); *Brown-Forman Distillers v. New York State Liquor Authority* 476 U.S. 573 (1986) (holding unconstitutional a New York statute requiring a distiller to charge the same prices in other states that it did in New York during a particular timeframe).

<sup>78</sup>Id. Though not technically a state, Puerto Rico is treated like one for these purposes.

<sup>79</sup>Id.

<sup>80</sup>*See Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200 (2<sup>nd</sup> Cir. 2003) (restrictions on direct cigarette sales, although burdening out-of-state sellers more, were constitutional because of the legitimate local interest in preventing cigarette sales to minors.)

<sup>81</sup>*See* 15 California Food & Agriculture Code. 35891 (requiring bimonthly inspections for market milk).

<sup>82</sup>*See, e.g. Oklahoma Statutes* 2-7-417 (requiring permitting and inspection for the facilities of raw milk distributors); Arizona Administrative Code 3-2-805 (requiring approved bottling equipment be used for raw milk production).

<sup>83</sup>Virginia Department of Agriculture and Consumer Services. “Frequently Asked Questions.” at <http://www.vdacs.virginia.gov/standards/questions.html> (last visited April 24, 2005); Indiana Code 15-5-13-11 (imposing \$50 inspection fee on pet foods)

Minnesota has a similar requirement. [add cites]

The third advantage to the pet food strategy is that while no state bars raw milk as animal food, yet permits it for human consumption,<sup>84</sup> several states treat raw milk sold for animals more leniently than raw milk sold for human consumption. Alaska , Florida, North Carolina, North Dakota and Tennessee, for example, all permit the use of raw milk as animal feed while banning it for human use.<sup>85</sup>

States that have separate regulations banning the use of raw milk as animal feed do not permit use of raw milk by humans.<sup>86</sup> The only state to officially recognize the cover strategy of selling raw milk as pet food has been Ohio, which bars all raw milk sale. Its Department of Agriculture posted on its website a response to the inquiry “May I purchase raw milk for my family’s consumption if it is labeled as pet food?”<sup>87</sup> The Department of Agriculture’s answer is ‘no,’ because of Ohio laws barring the sale of raw milk to consumers<sup>88</sup> and as animal feed.<sup>89</sup>

The Department concludes that raw milk is illegal for animals because the Ohio Administrative Code adopts the standards of the Association of American Feed Control Officials (“AAFCO”)<sup>90</sup> as definitions of feed ingredients by reference.<sup>91</sup> The posted response does not explain further, but a separate regulation requiring single ingredient feeds to have an AAFCO-approved product name<sup>92</sup> does seem to bar the sale of raw milk for pets in Ohio. The raw milk could not be labeled as milk, nor as raw milk.<sup>93</sup> The only state to explicitly

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<sup>84</sup> See “An Overview of U.S. State Milk Laws.” at <http://www.realmilk.com/milk-laws-1.html> (last visited April 24, 2005).

<sup>85</sup> Id.

<sup>86</sup> Id.

<sup>87</sup> “May I purchase raw milk for my family’s consumption if it is labeled as pet food?” at <http://www.ohioagriculture.gov/dairy/faqs/FAQ1.pdf>

<sup>88</sup> The Department response cites an exception for retailers who have been engaged in the sale of raw milk since before October 31, 1965, but none of these exist. Ohio Revised Code Sec. 917.04.

<sup>89</sup> “May I purchase raw milk for my family’s consumption if it is labeled as pet food?” at <http://www.ohioagriculture.gov/dairy/faqs/FAQ1.pdf>

<sup>90</sup> Which were developed with FDA guidance. Final Rule. “Standards for Animal Food and Food Additives in Standardized Animal Food.” 18 Fed. Reg. 4293.

<sup>91</sup> Ohio Administrative Code 901:5-7-01 Definitions and Terms.

<sup>92</sup> Ohio Administrative Code 901:5-7-011 Commercial Feeds.

<sup>93</sup> A company could add colostrum or some other ingredient and then term the resulting product Lacteal Secretion Delight, perhaps.

bar the use of non-AAFCO-approved ingredients in animal feed is Alabama, however, which also bars raw milk for human consumption.<sup>94</sup>

Thus the labeling of raw milk as pet food for introduction into interstate commerce, in addition to skirting FDA regulations, lets dairies ship raw milk to states that have banned raw milk sales by adopting the PMO or a similar ordinance, exempts dairies from most licensing and inspection requirements in all states save those where the dairies produce milk, and opens up a market in states that ban raw milk for human consumption yet allow it for animals.

## **B. The Frozen Milk Strategy**

The pet food strategy is the only successful one for interstate traffickers in raw milk. Two other tactics pioneered by Organic Pastures Dairy have failed. The first of these is freezing milk.

FDA sent a warning letter on February 24, 2005 to Organic Pastures Dairy because of their sales of frozen raw milk.<sup>95</sup> As explained in a news release issued by the Weston A. Price Foundation, a nonprofit organization advocating the use of raw milk, Organic Pastures Dairy started marketing frozen milk in 2004 in a partnership with the alternative medicine/health food site Mercola.com.<sup>96</sup> The release argued that the requirement that

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<sup>94</sup>Ala. Admin. Code r. 80-1-9-.02 (2004) "Pet Food Standards"

<sup>95</sup>"Organic Pastures Dairy Company Warning Letter." at [http://www.fda.gov/foi/warning\\_letters/g5215d.htm](http://www.fda.gov/foi/warning_letters/g5215d.htm) (last visited April 24, 2005).

<sup>96</sup>"Organic Pastures Dairy Company Signs Raw Dairy Products Internet Sales Agreement with Mercola.com," at

milk be in final package form for direct human consumption did not apply to frozen milk, because that milk is not in “final consumable form.”<sup>97</sup> This wording is unclear, but presumably the release takes the position that either frozen milk is not in ‘final package form’ or that because the milk must be defrosted before being consumed, it is not for ‘direct human consumption,’ since the intermediate step of defrosting prevents consumption from being ‘direct.’

The FDA warning letter, however, states that “[t]hough your products are shipped in a [redacted] state, your products are still considered to be in final package form for human consumption.”<sup>98</sup> The phrase “[redacted]” only makes sense if the missing term is “frozen.” It is difficult to find fault with the FDA response; there is nothing about the phrase “final package form” which excludes a box of frozen milk. Further, the intent of the pasteurization regulation to apply the “final package form” exception to permit out-of-state shipments to pasteurization plants, not shipments of unpasteurized frozen product to consumers.<sup>99</sup>

### C. The Dietary Supplement Strategy

An earlier Organic Pastures attempt to skirt the FDA regulations by adding colostrum to milk and classifying it as a dietary supplement also appears unsuccessful. A 2003 press release from the Weston A. Price Foundation argued that the inclusion of colostrum, a form of milk secreted cows immediately after giving birth that “looks and tastes just like regular raw milk,” can be legally distributed out-of-state because the

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[http://www.westonaprice.org/federalupdate/aa2004/infoalert\\_072604.html](http://www.westonaprice.org/federalupdate/aa2004/infoalert_072604.html).

<sup>97</sup>Id.

<sup>98</sup>“Organic Pastures Dairy Company Warning Letter.” at [http://www.fda.gov/foi/warning\\_letters/g5215d.htm](http://www.fda.gov/foi/warning_letters/g5215d.htm) (last visited April 24, 2005).

<sup>99</sup>Final Rule. “Milk, Lowfat Milk, and Skim Milk, Pasteurization Requirements for Fluid Milk Products for Consumer Use.” 52 Federal Register 29509 (August 10, 1987).

inclusion of colostrum prevents it from being a “dairy product.”<sup>100</sup>

The release announces California approval as a dietary supplement for a colostrum product sold by Organic Pastures Dairy. Two years after the release, Organic Pastures Dairy’s raw colostrum products are not sold outside of California for human consumption.<sup>101</sup> The press release’s analysis is incorrect.

Dietary supplements must meet several requirements; colostrum could qualify as such a supplement for FDA purposes,<sup>102</sup> but classification as a dietary supplement would not exempt it from the requirements for foods: “Except for purposes of section 201(g) [treating products which make disease treatment claims under the regulatory regime for drugs], a dietary supplement shall be deemed to be a food within the meaning of this Act.”<sup>103</sup>

Despite colostrum’s exclusion from the definition of “milk,” its pasteurization is still required by the FDA. FDA regulations for human food define “milk” as the “the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.”<sup>104</sup> This definition of milk excludes other animals, whose milk is defined as a “milk product.” Such products are “food products made exclusively or principally from the lacteal secretion . . . of a milk-producing animal. . . [such as] cows, goats, sheep and water buffalo.”<sup>105</sup> Use of the phrase “practically free from colostrum” would be meaningless if colostrum

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<sup>100</sup> “Action Alert: Raw colostrum approved in California.” at [http://www.westonaprice.org/federalupdate/aa2003/actionalert\\_083003.html](http://www.westonaprice.org/federalupdate/aa2003/actionalert_083003.html) (last visited April 24, 2005).

<sup>101</sup> “Organic Pastures Dairy Company – Order Now!” at <http://www.organicpastures.com/ordernow/>

<sup>102</sup> See 21 U.S.C.S. § 321(ff) (as amended by the Dietary Supplement Health and Education Act of 1994). Colostrum would meet the requirements that a supplement contain vitamins, minerals, herbs, or amino acids; it would have to be labeled as a dietary supplement and “not represented for use as a conventional food,” and its ingredients would have to had been approved for use before the Act’s passage, or would require FDA premarket notification.

<sup>103</sup> *Id.*

<sup>104</sup> 21 C.F.R. 133.3. The regulation requiring pasteurization of all “milk and milk products” shipped in interstate commerce does not refine or depart from this definition, as the sale of cheese does. 21 C.F.R. 1240.61.

<sup>105</sup> 21 C.F.R. 1240.3(j).

did not count as a “lacteal secretion.” Classification as a dietary supplement does not prevent regulation as a “food product,” and thus FDA regulations requiring pasteurization of milk products would prevent interstate shipment of raw colostrum for human consumption.

#### D. The Cow Share Strategy

One attempt to elude raw milk regulation is by buying “cow shares,” or engaging in “cow leasing.” Statutes that ban the “sale” of milk do not necessarily apply to these transactions, in which a customer purchases (or rents) a part ownership interest in a cow and in return receives the proceeds of that ownership interest in the form of unpasteurized milk.<sup>106</sup> These transactions are not mere technical evasive maneuvers, but instead have substance: a Virginia cow share agreement renders the shareholder responsible for any unusual veterinary bills the cow might incur, for example.<sup>107</sup> A farm that distributes raw milk by selling “farm shares” gathers its shareholders twice a year for voting on farm activities.<sup>108</sup>

State response to cow sharing has been mixed. Wisconsin authorized a cow share program, but eventually shut it down after a Salmonella outbreak<sup>109</sup> – the Wisconsin statutes barred “distribution” of raw milk as well as its “sale,” however, so it is not a useful guide to understanding to what extent cow shares can

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<sup>106</sup>Katy McLaughlin. “Got Raw Milk? Not Unless You Own Your Own Cow; Farmers Offer Bovine Stakes To Bypass Health Rule; Wisconsin Sours on Plan.” Wall Street Journal: Sep 11, 2003. pg. A.1.

<sup>107</sup>“Hedgebrook Farms” at <http://www.hedgebrook.com/cowboarding.asp> (last visited April 24, 2005)

<sup>108</sup>McLaughlin.

<sup>109</sup>Id; *see supra* at note 19 for details of the outbreak. As the Wall Street Journal reports, the defeat of the cow sharing plan in Wisconsin led to the incorporation of the underlying farm and sale of its shares, with attendant involvement in the business of the dairy by shareholders. Katy McLaughlin. “Got Raw Milk? Not Unless You Own Your Own Cow; Farmers Offer Bovine Stakes To Bypass Health Rule; Wisconsin Sours on Plan.” Wall Street Journal.: Sep 11, 2003. pg. A.1.; “Overview of U.S. State Milk Laws” at <http://www.realmilk.com/milk-laws-3.html> (last visited April 24, 2005).



circumvent “sale” language.<sup>110</sup> Other states such as Michigan have not challenged the practice.<sup>111</sup>

The only state that has taken legislative action in response to cow sharing is North Carolina; it changed the statutory definition of “sale” of raw milk to include the purchase and sale of cow shares, and such arrangements are now illegal in that state.<sup>112</sup>

Cow shares have not been tested against FDA regulations on interstate sale; the cow share programs mentioned in a *Wall Street Journal* article on the subject, for example, involved sales of milk on farms rather than shipment to out-of-state shareholders.<sup>113</sup> One Virginia farm that offers “cow boarding” agreements will deliver to shareholders, but only within Northern Virginia.<sup>114</sup>

Given the expense involved in shipping raw milk, there may be no consumer willing to commit to buying a share of an out-of-state cow. If one did buy a share, the legality of the arrangement would depend on whether milk shipped in this fashion was “delivered into interstate commerce” within the meaning of FDA regulations.<sup>115</sup> This phrase appears broad enough to encompass the cow sharing practice if FDA chose to enforce it, since the regulation does not require a literal “sale” of the milk.

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<sup>110</sup>Wisconsin Statutes 97.24 “Requirements for milk and fluid milk products.”

<sup>111</sup>Katy McLaughlin. “Got Raw Milk? Not Unless You Own Your Own Cow; Farmers Offer Bovine Stakes To Bypass Health Rule; Wisconsin Sours on Plan.” *Wall Street Journal*.: Sep 11, 2003. pg. A.1.; “Overview of U.S. State Milk Laws” at <http://www.realmilk.com/milk-laws-3.html> (last visited April 24, 2005).

<sup>112</sup>“Sale’ or ‘sold’ shall mean any transaction that involves the transfer or dispensing of 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 or herd.” North Carolina General Statutes. 130A-279.

<sup>113</sup>Katy McLaughlin. “Got Raw Milk? Not Unless You Own Your Own Cow; Farmers Offer Bovine Stakes To Bypass Health Rule; Wisconsin Sours on Plan.” *Wall Street Journal*.: Sep 11, 2003. pg. A.1.

<sup>114</sup>“Hedgebrook Farm” at <http://www.hedgebrook.com/cowboarding.asp> (last visited April 24, 2005).

<sup>115</sup>21 C.F.R. § 1240.61.

## IV. Policy

Should the FDA act in response to the pet food strategy? A few salient possibilities for regulatory action by the FDA include banning all intrastate raw milk sales, banning raw milk sales in animal feed, and merely enforcing existing regulations. Since banning all intrastate sales of raw milk would have be broader than necessary to solve the circumvention of current FDA regulations, this Part will consider only the latter two possibilities.

The strongest case for FDA action is twofold. First, the pet food strategy in many situations prevents states from stopping interstate sale of raw milk as pet food to their citizens without amending their statutes. Second, because raw milk sales in interstate commerce will occur primarily over the Internet, purveyors of raw milk can lace their websites with misleading health claims<sup>116</sup> that lull consumers into a false sense of security and obscure the dangers of raw milk.

Consider the claims made by Organic Pastures Dairy: raw milk “strengthens the immune system” and “has been used effectively to assist Autistic [sic] children,” unlike pasteurized milk, which “causes allergies.”<sup>117</sup> The site also engages in a bit of obnoxious paralepsis by declining to list the fifty diseases “positively effected [sic]” by raw milk, but instead directing the visitor to various websites that will make the more brazen claims.<sup>118</sup> If people are being misled into buying raw milk products, or buy such products because of their association with “natural” or “organic” food, this state of affairs hurts the argument that a purchaser should be able to decide that she likes the taste of raw milk enough to incur a few health risks.

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<sup>116</sup>The Food, Drug, and Cosmetics Act’s definition of “labeling” is “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C.A. § 321(m). A dairy’s website does not “accompany” a jug of milk, and is thus exempt from restrictions on health claims.

<sup>117</sup>“Organic Pastures Dairy Company – FAQ” at <http://www.organicpastures.com/faq/> (last visited April 24, 2005).

<sup>118</sup>Id. Under *Consumers Union v. Alta-Dena Certified Dairy*, *supra* at note 22, it is not clear that Organic Pastures may make these claims under California law.

One might respond that milk sold for pet food only carries the attendant implication that it is not safe for human consumption. This could counteract marketing puffery by the dairy selling the milk. The owner of Peaceful Pets has stated that many people request her to sell milk for human consumption<sup>119</sup> – the “pet food strategy” does not overcome their qualms about eating food legally served only to pets, or they would just buy the milk as currently sold. Even where a producer like Organic Pastures Dairy sells the same milk for human consumption as for animal consumption, the “pet food only” label still serves as a deterrent to consumers.

One might also argue in response to the pro-regulation position that the policy arguments are weaker for a ban on the interstate sale of raw milk than on the sale of intrastate raw milk: while the normal consumer of raw milk in California is more likely to possess only a high school education than a consumer of pasteurized milk,<sup>120</sup> anyone wealthy enough to pay \$50 to ship a \$68 gallon of cream<sup>121</sup> is more likely to be privileged and educated, and thus to have access to information about the health risks of raw milk. Alternatively, for the gourmet cook or amateur cheesemaker who derives great utility from being able to buy raw milk, there are far fewer innocent victims at these prices.

Further, even for the very wealthy, raw milk as pet food is unlikely to present anyone with much risk, not because few people consume it, but because the process of interstate shipment of milk is so expensive and cumbersome that few people will consume it very often. The Centers for Disease Control estimate that a consumer of raw milk during 1983 faced a 1 in 2,000 chance of contracting *Salmonella dublin* assumed consumption of a daily pint.<sup>122</sup>

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<sup>119</sup>Mitchell Kline. “Advocates of raw milk form dairy underground.” *The Tennessean* Dec. 28, 2004 available at <http://www.tennessean.com/local/archives/04/12/63400735.shtml> (last visited April 24, 2005).

<sup>120</sup>Headrick ML, Badgaleh T, Klontz KC, Werner SB. “Profile of raw milk consumers in California.” *Public Health Reports* 112:418 (1997).

<sup>121</sup>“Organic Pastures Dairy Company – Order Now!” at <http://www.organicpastures.com/ordernow/> (last visited April 24, 2005).

<sup>122</sup>Centers for Disease Control. “*Salmonella Dublin* and Raw Milk Consumption – California.” *Morbidity and Mortality*

There are also some positive externalities to an interstate market for raw milk. It can provide very high profits to small dairies and thus help family dairy farms stay afloat.<sup>123</sup> Many people attach some existence value to the family farmer. The specter of product liability will likely prevent raw-milk-as-pet-food from becoming a very large-scale operation.

An advocate of regulation would rejoin that general arguments about the merits of bothering with the interstate transfer of raw milk are not applicable to FDA policy in this area, because the FDA has already committed to an interstate ban on raw milk. But if regulating the interstate sale of raw milk is barely worth FDA resources – perhaps reflected in the fact that it had to be forced to do so initially by a court order<sup>124</sup> – this fact bears on the question of whether it is worth regulating pet food solely to reduce the possibility that consumers will purchase raw milk as pet food and then drink it themselves.

Banning raw milk as pet or animal food is also not costless. Two states that have addressed the use of raw milk as animal feed have required a dye be applied to the milk rather than banning it.<sup>125</sup> To the extent that there are legitimate reasons for farmers to purchase raw milk from a separate state for their farms, an FDA regulation could have unintended disadvantages for those farmers.

Because raw milk still poses significant risks, the FDA should continue to enforce its ban on interstate sale. The pet food strategy raises the costs of FDA action – a new regulation must be promulgated – and lowers the benefits, since the “pet food” designation already warns off consumers. On balance, therefore, it would

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Weekly Report 33(14) p. 196-198 (April 13, 1984). *available at* <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000318.htm> (last visited April 24, 2005).

<sup>123</sup> See McLaughlin *supra* at note 113 (describing how raw milk sales saved a family farm).

<sup>124</sup> See *supra* at note 9.

<sup>125</sup> 25 C.R.S. 114-114-114. “Unlawful acts.” (Such acts include selling raw milk for animal consumption unless treated with a dye.). Texas requires dye in raw milk for animal feed as a matter of policy “An Overview of U.S. State Milk Laws” *at* <http://www.realmilk.com/milk-laws-5.html> (last visited April 24, 2005)

be a better use of FDA resources to target the poor and disadvantaged who are not aware of the risks they are taking with raw milk<sup>126</sup>, as the agency is already doing<sup>127</sup>, to continue to test raw milk dairies for pathogens<sup>128</sup>, and to pursue action against raw milk as pet food if its human consumption as pet food becomes more prevalent.

## V. Conclusion

The popularity of cow share programs demonstrates that it is very difficult to prevent farmers and customers from exchanging raw milk for money. Whether raw milk consumers long to get closer to nature by consuming “organic” and unprocessed food or simply cannot do without the superior flavor or raw milk, they are as eager to buy raw milk as cash-strapped dairy farmers are to sell it. The sales are more important to both parties than many other transactions.

Recent FDA experience with the interstate portion of these sales should be frustrating for regulators. The warning letter sent to Organic Pastures Dairy Company in February<sup>129</sup> is no longer relevant, since the company has cycled from the frozen milk strategy to the pet food strategy.

Rather than expending more resources in a potentially futile fight with the pet food shippers – who knows

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<sup>126</sup>Headrick ML, Badgaleh T, Klontz KC, Werner SB. “Profile of raw milk consumers in California.” *Public Health Reports* 112:418 (1997).

<sup>127</sup>The FDA recently issued a warning describing disease risk in unpasteurized Mexican soft cheese, for example. Maribel Villiava. “FDA warns Hispanics about queso fresco.” *El Paso Times* April 20, 2005. *available at* <http://www.borderlandnews.com/apps/pbcs.dll/article?AID=/20050420/NEWS/50420003/1001> (last visited April 24, 2005)

<sup>128</sup>Before issuing a warning letter to Organic Pastures Dairy, the FDA tested its production facilities extensively. “Organic Pastures Dairy Company Warning Letter.” *at* [http://www.fda.gov/foi/warning\\_letters/g5215d.htm](http://www.fda.gov/foi/warning_letters/g5215d.htm) (last visited April 24, 2005).

<sup>129</sup>*Id.*

what their next strategy will be? – the FDA should focus on persuading consumers of raw milk that drinking milk in its natural, unpasteurized state is not a healthier alternative to drinking pasteurized milk. If well-informed organic food diehards are still willing to pay exorbitant sums and bear some disease risks to get their raw milk fix, then the FDA has more pressing tasks than to stand in their way.