UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ORGANIC PASTURES DAIRY COMPANY, *et al.*, Defendants.	1:08-CV-01786-OWW-GSA MEMORANDUM DECISION AND ORDER RE: UNITED STATES OF AMERICA'S MOTION FOR SUMMARY JUDGMENT (Doc. 22.)

I. INTRODUCTION

This matter is before the Court on the government's motion for summary judgment and entry of a permanent injunction. The government seeks to permanently enjoin Defendants Organic Pastures Dairy Company and Mark McAfee from distributing and/or introducing raw milk across state lines, in contravention of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The government's request for injunctive relief is based on separate agreements signed by Defendants in December 2008, resolving criminal cases against them. In the agreements, Defendants acknowledged that Organic Pastures' employees violated the FDCA by distributing raw milk to out-of-state customers in 2007.

Defendants do not dispute the liability portions of the United States' motion. Instead, they oppose the breadth of the government's proposed relief, arguing the terms of the permanent injunction are duplicative of their criminal plea arrangements, impose on California's regulation of the raw milk industry, are financially crippling, and constitute a personal attack on Mr. McAfee. Defendants also contend that they ceased distributing raw milk into interstate commerce following their criminal pleas, therefore the permanent injunction is unnecessary.

II. FACTUAL BACKGROUND

The following facts are taken from the parties' submissions in connection with motion for summary judgment. The facts are largely undisputed.[1]

A. The Parties

Defendant Organic Pastures Dairy Company ("Organic Pastures") is a California Corporation that maintains its principal place of business in Fresno, California. (SUF 1.) Organic Pastures is engaged in milking cows and packaging, labeling, selling, and distributing raw milk and raw milk products including cream,

[1] Unless otherwise noted, the facts are undisputed. (See Stmt. of Undisp. Facts in Support of Def.'s Mot. for Summ. J. ("SUF"), filed by the United States on Dec. 8, 2009). Defendants object to much of the evidence submitted by the United States on various grounds. Virtually all of Defendants' objections are without merit. To the extent that Defendants' sole dispute with facts is based upon the inadmissability of the government's evidence, and is not challenged by any admissible evidence submitted by Defendants, these facts are viewed as undisputed.

butter, buttermilk, and colostrum. (SUF 3.) It has over 60,000 customers in California, selling its products to retailers, including national retailer "Whole Foods Market," and via its website (www.organicpastures.com).

Defendant Mark McAfee ("McAfee") is the co-founder and managing member of Organic Pastures. (SUF 2.) He is responsible for the day-to-day operations of Organic Pastures, including all manufacturing and distributing operations. (Id.)

B. Defendants' Interstate Raw Milk Practices

According to the United States, Defendants have a long history of selling raw milk and raw milk products to out-of-state customers. In late 2008, pursuant to separate "Deferred Prosecution Agreements," Defendants acknowledged that Organic Pastures' employees distributed raw milk to out-of-state customers in 2007. Specifically, Defendants admitted that two shipments were made to out-of-state customers "with the knowledge and consent of Organic Pastures" and were labeled as "pet food" to avoid detection:

> On October 10, 2007, one or more of defendant Organic Pastures' agents or employees, with the knowledge and consent of Organic Pastures, caused a box of raw milk and dairy products, labeled as or otherwise represented to be "pet food," to be sent by defendant Organic Pastures from Fresno, California to Renton, Washington, knowing that the intended use of such foods and/or dietary supplements was for human consumption. The box contained one ½ gallon of unpasteurized raw whole milk and one ½ gallon of unpasteurized raw Super Choco Colostrum. The invoice number was #356546557.
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> On October 16, 2007, one or more of defendant Organic Pastures' agents or employees, with the knowledge and consent of Organic Pastures, caused one box of raw milk and dairy products, labeled as or otherwise

> **represented to be "pet food," to be sent by defendant Organic Pastures from Fresno, California to Reno, Nevada, knowing that the intended use of such foods and/or dietary supplements was for human consumption. The box contained one ½ gallon of unpasteurized raw whole milk and one pint of unpasteurized raw colostrum. The invoice number was #165465524.**
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> **These products were foods and/or dietary supplements, and were misbranded when so introduced into or delivered for introduction into interstate commerce, in that they were falsely and misleadingly labeled as, or otherwise represented to be "pet food," when they were actually intended for human consumption, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1).**

(Doc. 24-14, Defendant McAfee's "Deferred Prosecution Agreement," at 9:3-9:23.[2])

In addition to the criminal plea agreements, the government supports its motion with evidence gathered by the FDA during its investigation of Organic Products. This evidence consists of packaging labels, Organic Pastures' web content, website testimonials, statements made by Organic Pastures' employees, and McAfee's own statements to FDA investigators and various news outlets. First, the government points to the exterior labeling of Defendants' shipping containers, which stated that the products "are labeled and intended for: 'Pet Food' consumption only."[3] Nowhere on the individual retail products was there a label indicating that the products were to be limited to pet consumption or identifying the products as pet food. (SUF 16-17.) However,

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[2] Identical language is contained in Defendant Organic Pastures' "Plea Agreement," signed on November 26, 2008. (Doc. 24-15, 10:9-10:26.)

[3] The relevant shipping containers were for products sold in interstate commerce in 2007.

the individual retail products bore statements such as "the best milk you'll ever taste," and that Organic Pastures products "are highly recommended by [...] thousands of happy healthy people." (SUF 17.) On the United States' account, a prominent packaging statement on individual retail products clearly shows that Defendants' raw milk and raw milk products are intended for human consumption:

> Raw (unpasteurized) milk and raw milk dairy products may contain disease-causing micro-organisms. Persons at highest risk of disease from these organisms include newborns and infants; the elderly; pregnant women; those taking corticosteriods, antibiotics or antacids; and those having chronic illnesses or other conditions that weaken their immunity.

(SUF 18.)

The United States also contends that statements by Defendants' employees demonstrate that Organic Pastures distributed and/or distributes raw milk and raw milk products in interstate commerce for human consumption. In particular, the United States points to an email from Kaleigh McAfee, Manager of Sales and Marketing at Organic Pastures, to an undercover FDA investigator in September 2007. In the email, Ms. McAfee states that Organic Pastures can "absolutely" send raw milk to all fifty states and espouses the health benefits of raw milk - that it "cures asthma." (SUF 21.) The email does not state that raw milk is intended to be used as pet food. (SUF 22.)

The United States identifies another email, this one sent by Defendant McAfee to an FDA public affairs specialist in 2007. In the email McAfee stated that "when raw milk is tested and labeled as intended for direct human consumption it is extremely safe."

(SUF 23-24.) McAfee also indicated his intention to sell raw milk to humans and declared that "there is nothing the FDA can do about it." (SUF 25.)

In a 2005 Portland Tribune article, Defendant McAfee stated that Organic Pastures consciously labels its raw milk products as "pet food" to avoid federal regulation of the interstate sale of raw milk:

> The neat thing about the law is that it can be interpreted in many ways. The state of Oregon understood that there was a loophole by putting a pet sticker on the product. And there's no regulation that you can't eat pet food, either. I am a revolutionist in this, and I won't overlook any loophole that will get the milk out there.

(SUF 55.)

The United States provides additional examples of Defendants' intent to distribute raw milk and raw milk products into interstate commerce for human consumption. The United States points to several statements made by Organic Pastures on its website concerning the "pet food" labeling: "[Organic Pastures] has creatively labeled its products for sale outside of California in such a way that it is not illegal under the law [...] this provides raw food drinkers the freedom to choose a raw product over a dead product. It is also great pet food." (SUF 50.)

According to the United States, Defendants' employees have also made statements reflecting Organic Pastures' intention to sell raw milk in interstate commerce. In July 2005, an FDA investigator ordered several raw milk products through Organic Pastures' website. (SUF 52.) When the investigator received the items, he called Organic Pastures to inquire about the pet food label. (Id.)

The Organic Pastures sales representative responded that the product was safe for humans and that the "'pets only' sticker is a legal loophole for us to sell out of state." (Id.)

C. Related Criminal Proceeding

While this case was pending, Defendant Organic Pastures faced similar charges in a criminal action involving similar conduct. The criminal matter concluded in settlement by plea agreement on December 22, 2008 and was approved by Magistrate Judge Sandra M. Snyder on January 9, 2009. (SUF 69.) Pursuant to the plea agreement, Defendant Organic Pastures pled guilty to two counts of misdemeanor introduction and delivery for introduction into interstate commerce of misbranded food, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). (SUF 70.) Defendant McAfee entered into a deferred prosecution agreement whereby he agreed to the filing of a two count information charging him and Organic Pastures with the same violations. (SUF 71.)

In these agreements, both Defendants admitted that: (1) on two separate occasions "one or more of defendant Organic Pastures' agents or employees, with the knowledge and consent of Organic Pastures, caused [a] box of raw milk and dairy products, labeled as or otherwise represented to be 'pet food,' to be sent by defendant Organic Pastures" into interstate commerce, "knowing that the intended use of such foods and/or dietary supplements was for human consumption;" and (2) Organic Pastures' raw milk and raw milk products "were foods and/or dietary supplements, and were misbranded when so introduced into or delivered for introduction into interstate commerce, in that they were falsely and

misleadingly labeled as, or otherwise represented to be 'pet food,' when they were actually intended for human consumption in violation of [21 U.S.C. §§ 331(a) and 333(a)(1).]" (SUF 72-73.)

III. PROCEDURAL BACKGROUND

On November 20, 2008, the United States filed a civil complaint for permanent injunction, alleging that Defendants violated: (1) 21 U.S.C. § 331(a), by introducing or delivering, and causing to be introduced or delivered, into interstate commerce food that is misbranded within the meaning of 21 U.S.C. § 343(a)(1); (2) the Public Health Services Act ("PHSA"), 42 U.S.C. § 264, by distributing raw milk and raw milk products in interstate commerce in final package form for human consumption; and (3) 21 U.S.C. § 331(d), by introducing or delivering, and causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(I). (Doc. 1.)

Defendants filed their Answer to Plaintiff's Complaint on January 20, 2009. (Doc. 2.)

The United States moved for summary judgment on December 8, 2009. (Doc. 22.) In support of its motion, the United States submitted: (1) a Memorandum of Points and Authorities ("Memorandum"); (2) a Statement of Undisputed Facts in Support of its Motion;; (3) the Declaration of Barbara Cassens; (4) the Declaration of Jeanne M. Weishaar; (5) the Declaration of Stefano Luccioli, M.D.; (5) a "Proposed Order of Permanent Injunction;" and (6) several hundred pages of exhibits, most of which appear to

be related to the FDA's investigation of Organic Pastures. (Docs. 22-2 through 24-16.)

Defendants opposed the United States' motion on January 19, 2010. (Doc. 31.) In support of its opposition, Defendants submitted: (1) a Memorandum opposing the motion ("Opposition"); (2) the Declaration of Mark McAfee; (3) the Declaration of J. Kenneth Gorman; and (4) a Request for Judicial Notice.[4] (Docs. 33 through 36.)

Defendants do not dispute the liability portion of the United States' motion, i.e., they acknowledge that they violated the FDCA and PHSA by introducing and/or distributing raw milk into interstate commerce in 2007. They also concede that they violated the "unapproved raw drugs" provision of the FDCA. Instead, they oppose the motion on grounds that the relief proposed is duplicative of their criminal plea arrangements, inconsistent with the State of California's regulation of the raw milk industry, cost-prohibitive, and constitutes a personal attack on Mr. McAfee.

IV. LEGAL STANDARD

Summary judgment/adjudication is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56©. The movant "always bears the initial

[4] Defendants request judicial notice of California Food and Agricultural Code §§ 32731 through 36061. (Doc. 34.) As the United States does not object and the matters are of public record, the request is GRANTED.

responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted).

Where the movant will have the burden of proof on an issue at trial, it must "affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party." *Soremekun v. Thrifty Payless*, Inc., 509 F.3d 978, 984 (9th Cir. 2007). With respect to an issue as to which the non-moving party will have the burden of proof, the movant "can prevail merely by pointing out that there is an absence of evidence to support the nonmoving party's case." *Soremekun*, 509 F.3d at 984.

When a motion for summary judgment is properly made and supported, the non-movant cannot defeat the motion by resting upon the allegations or denials of its own pleading, rather the "non-moving party must set forth, by affidavit or as otherwise provided in Rule 56, 'specific facts showing that there is a genuine issue for trial.'" *Soremekun*, 509 F.3d at 984. (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)). "A non-movant's bald assertions or a mere scintilla of evidence in his favor are both insufficient to withstand summary judgment." *FTC v. Stefanchik*, 559 F.3d 924, 929 (9th Cir. 2009). "[A] non-movant must show a genuine issue of material fact by presenting *affirmative evidence* from which a jury could find in his favor." *Id.* (emphasis in original). "[S]ummary judgment will not lie if [a]

dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. In determining whether a genuine dispute exists, a district court does not make credibility determinations; rather, the "evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255.

V. DISCUSSION

According to the United States, Defendants' history of distributing raw milk and raw milk products across state lines establishes that Defendants violated 21 U.S.C. § 331(a) and 42 U.S.C. § 264. The United States also contends that Defendants marketing of raw milk as a "therapeutic cure" for asthma and other health conditions violated 21 U.S.C. § 331(d)'s bar on "unapproved new drugs." Pursuant to 21 U.S.C. § 332(k), the United States seeks an injunction forbidding Defendants from engaging in either of these practices.[5]

Defendants do not dispute the liability portions of the United States' motion. In particular, Defendants acknowledge that they introduced and/or distributed raw milk into interstate commerce in 2007 in violation of 21 U.S.C. § 331(a) and 42 U.S.C. § 264(a). (See Doc. 31, 4:19-4:20 ("[Defendants] do[] not dispute that the deferred prosecution agreement and plea agreement bar any argument

[5] The government provides a "Proposed Order of Permanent Injunctive Relief," outlining the proposed terms for injunctive relief. (Doc. 22-4.) Defendants stipulate to the initial three paragraphs of the proposed injunction. Defendants, however, object to the remainder of the proposed injunction on various grounds.

[on] liability on the charges of mislabeling its conduct [....]")).[6] Nor do Defendants oppose the government's "unapproved new drugs" claim, which was advanced pursuant to 21 U.S.C. § 331(d).[7] Defendants do, however, object to the breadth of the government's proposed injunction.

Section 332(a) of Title 21 of the United States Code empowers district courts to enjoin violations of § 331. 21 U.S.C. § 332(a). Here, the unopposed evidence shows that Defendants have violated the FDCA by distributing misbranded raw milk at least two times since 2007; it also demonstrates that Defendants impermissibly promoted the therapeutic benefits/capabilities of raw milk. (See SUF 5, 11, 9-79; Doc. 24-14, McAfee's "Deferred Prosecution Agreement.") Because the government has established that Defendants violated §§ 331(a) and (d) of the FDCA, the government is entitled to an injunction if it also establishes a cognizable danger of recurrent violations. *See United States v. Odessa Union*

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[6] According to Defendants, although "the plea agreements establish liability as a matter of law, they do not establish the penalty as a matter of law, and the drastic remedies sought by the Federal government are not warranted in any respect." (Doc. 31, 5:16-5:18.)

[7] In opposing the United States' motion for summary judgment, Defendants initially argue that the government did not "present any evidence that any consumer purchased raw milk with the expectation that it was a 'drug.'" Defendants also challenge the evidentiary basis to elevate raw milk to "drug" status. Defendants, however, withdraw from those positions, conceding that the United States satisfied its "new drug" claim under 21 U.S.C. § 331(d). Specifically, Defendants state that the "classification of raw milk as a drug is dubious at best, and in any case, *moot*." (Doc. 31, 5:19-5:20) (emphasis added). Because Defendants did not oppose the United States' § 331(d) motion, a thorough analysis of § 331(d) and the interpreting case law is not required.

***Warehouse Co-op*, 833 F.2d 172, 176 (9th Cir. 1987)*; United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 28 (2d Cir. 1972) ("The passage of the [Food, Drug, and Cosmetic Act] is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained."). The probability of future violations may be inferred from past unlawful conduct.[8] *Odessa Union*, 833 F.2d at 176; *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 50 (E.D.N.Y. 2001) (citations omitted).**

The government asserts that because Defendants actively violated the FDCA in 2007 by shipping raw milk to out-of-state customers, they are reasonably likely to violate the FDCA in the future. The government applies the same reasoning to Defendants promotion of raw milk and raw milk products as a "therapeutic cure" for various health conditions. On the government's account, Defendants have "flouted the law for years," and the record is "replete with evidence suggesting that Defendants are likely to resume their illegal conduct with the criminal agreements are dissolved within a year."

Defendants contend that even if their past conduct violated the FDCA, they ceased much of the behavior complained of by the government years ago. Specifically, Defendants rejoin that the proposed injunction is "largely unnecessary" as they stopped shipping raw milk out-of-state in 2007 and have removed from

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[8] The probability of future violations may also be inferred based on Defendants' numerous statements of intent to ignore and violate the prohibition against interstate raw milk sales. *Id.* The government argues that Defendants are reasonably likely to violate the FDCA in the future based on Defendants' statements of intent to violate the FDCA's prohibitions against interstate raw milk sales.

Organic Pastures' website all claims/testimonials concerning raw milk's health benefits. Although Defendants' progress towards improvement and their intention to comply with FDCA requirements are relevant to the inquiry, the Ninth Circuit has emphasized that a past pattern of activity bears heavily on whether the offender is likely to violate the FDCA in the future. *See Odessa Union*, 833 F.2d at 176 ("the district court must weigh [the offender's] continuing [] problems in light of its extensive history of violations, since an inference arises from [the offender's] past violations that future violations are likely to occur."). Courts have also recognized the carry-over effects of marketing and promotional claims in actions arising under the FDCA. *See United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 574 (D.N.J. 2004).

Here, given the history of admitted violations by Defendants, as well as their acknowledgments concerning the promotion of raw milk's therapeutic effects, the government has established a likelihood of additional FDCA violations. *Odessa Union*, 833 F.2d at 176; *see also Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 574-76 (finding that likelihood of continuing FDCA violations was "great" despite the company's arguments that it had not violated the FDCA for many years.[9]). Given the uncontested facts, Defendants cannot

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[9] In *Lane Labs-USA*, the United States moved to permanently enjoin Defendants from distributing and marketing certain products made from shark cartilage. The Court found that Defendants violated the FDCA, §§ 331(a), 331(d), and 331(k), and issued a permanent injunction. In response to Defendants' arguments that it had ceased violated the FDCA, the Court stated:

> Defendants further contend that they have rectified

satisfy the burden to establish that "there is no reasonable expectation that the wrong will be repeated." *United States v. W.T. Grant*, 345 U.S. 629, 633 (1953).

That is not the end of the analysis, however. In FDCA cases, injunctive relief must be used sparingly, to prevent future harm, and not to punish past violations. *See United States v. Barr Laboratories, Inc.*, 812 F. Supp. 458, 487-88 (D.N.J. 1993) (citing *SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir. 1980)). A district court has considerable discretion in granting injunctive relief and in tailoring injunctive relief, but the relief must not be overly broad in light of the conduct of the enjoined party. *See generally Odessa Union*, 833 F.2d at 177*; see also United States v. Captain's Select Seafood, Inc.*, No. 08-CV-1658-PJS-RLE, 2009 WL 398081 at *2

> any past missteps [...] Defendants claim that they have cooperated with the FDA in every regard by complying with FDA inspections, permitting access to Lane Labs' facilities and supplying records and materials requested by the Government. Defendants argue that the broad reach of the requested injunction is meant to impermissibly punish Lane Labs for past violations that it has worked to rectify [...]
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> However, Defendants' past pattern of activity bears upon whether Lane Labs is likely to violate the FDCA in the future. Courts have recognized the carry-over effects of marketing and promotional claims in actions arising under the FDCA. Courts have also looked to a defendant's repeated violations when issuing injunctions in other types of cases [...]
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> Given Defendants' past pattern of behavior, in which Lane Labs has purposefully flouted the FDCA framework throughout the pendency of this lawsuit, this Court finds that an injunction of this scope is warranted.

(Id. at 573-75) (citations and quotations omitted).

(D. Minn. Feb. 17, 2009) (finding the government's injunction overly broad and disproportional in light of the challenged conduct).

Defendants oppose the government's proposed permanent injunction on a number of grounds. The substance of Defendants' arguments is that the proposed injunction is unneeded and overly broad. According to Defendants, the proposed injunction is unnecessary because Defendants ceased distributing raw milk in interstate commerce in 2007. Defendants also criticize the scope of the proposed injunction, arguing that it "give[s] the FDA unlimited, undefined discretion to order [Organic Pastures] to do, or stop doing, anything the FDA determines," which threatens Organic Pastures' financial viability.

The government responds that the proposed injunction in the case is no different than the injunctions in *Odessa Union*, 833 F.2d 172, *Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, and *United States v. Endotec, Inc.*, 06-CV-1281-ORL-18KRS, 2009 WL 3111815 (M.D. Fla. Sep. 28, 2009). Specifically, the government argues that the proposed injunctive relief is "both warranted and necessary to ensure that Defendants do not resume their unlawful conduct." As to FDA involvement, the government offers a similar take: the terms are "essential to enable the FDA to ensure [] compliance with the FDCA, the PHSA, and the regulations."

Here, the injunction sought by the government is overly broad in light of Organic Pastures' and McAfee's conduct. In particular, the government's proposed injunction would require a "signed written statement" from any purchaser agreeing that it "will not sell or distribute Defendants' raw milk products outside the state

of California." This would require *any* purchaser to sign such a statement, regardless of the type of buyer (individual or entity), location, size or distribution history. Such a provision is not tailored to either Organic Pastures' or McAfee's prior conduct and lacks an interstate nexus. Moreover, there is no evidence that Defendants have ever engaged in a "straw" purchase or a resale agreement involving interstate distribution. These arguments were developed during an exchange between the government's counsel and the Court during oral argument on March 12, 2010:

> **Court: Paragraph 11 [...] calls for the obtaining of written statements from any purchaser or a reseller that the person or entity will not sell outside the State of California and the defendants are required to maintain copies of the signed statements and make them immediately available to the FDA on request.**
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> **The Court has the concern that this paragraph does not say interstate. Conceivably, one way to read this paragraph is that every carton of milk that's sold or any raw milk product that is sold is going to require the consumer and the retailer and/or wholesaler to sign this statement. And that would, I think, have such a chilling effect on the conduct of business that it would put the defendant out of business. And because it says to any person or entity that purchases these products and holds these products for resale to any other person or entity. And so that could be consumer, that could be mom and pop -- any -- not even a retail establishment. At a fair or a theater or any place where milk products can be sold and then resold to other consumers. And if you've got the prohibition that it can't be done, in effect, what you're doing is you are making the defendant the enforcement arm of the FA to police on an industry wide basis [...] requiring that person to get the signed statement and then turn it over to the FDA or to have the defendant be the custodian, to make it available to the FDA for inspection.**
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> **When the prohibition is that they can't do it. And this adds a level of burden. We haven't had any statistics from the defendant as to how**

> many, if you will, resellers they sell to, But the Court can certainly conceive that this isn't just, for instance, grocery stores or other distributors who have large customer bases. This applies to anybody and everybody who's going to resell milk.
>
> Counsel: And Your Honor, you did -- I think the operative language in here is that it applies to entities that hold products for resale.
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> Court: Right.
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> Counsel: I think the FDA -- the government would be remiss in not including this paragraph to prevent the scenario where, you now, straw purchasers are middle men who are not named in the order and have no notice of the order can participate in a chain transaction that will milk or other raw milk products across [...]
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> Court: Well, for instance, is there one iota of evidence that the defendant has ever done this?
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> Counsel: Your Honor, the defendant's wrote [...] that their employees had knowledge that milk had been sold to people who were intending to take milk across state lines [...] the reason we are asking for written statements for people that are going to resell [raw milk] 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 [...] but the statement is here, you know, in part to almost protect the defendants for tho people they know are reselling this milk [...]
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> Court: Well, how about the prohibitory language if it were on a label that simply said not intended for resale if -- and again, though, it seems to me completely unworkable because of the various channels of distribution that these kinds of products are sold through.
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> My sense of it is -- I've heard what you said. It seems at best unprecedented and it seems unduly burdensome.

(Reporter's Transcript ("RT"), March 12, 2010, 27:12-30:19.)

Many of the proposed injunction's remaining provisions are similar. For example, the proposed injunction requires Defendants

to obtain written authorization from the FDA in advance of delivering raw milk products across state lines, which are already barred pursuant to 21 U.S.C. § 331(a) and by the 2008 agreements settling their criminal cases. The provision continues in perpetuity and does not provide an exception in the event the prohibition on the interstate sale of raw milk is repealed or changed. In that scenario, Defendants would need the written approval of the FDA to conduct a legal enterprise.

This case differs from those involving "adulterated food" under 21 U.S.C. § 331(a) and § 21 U.S.C. § 342.[10] At oral argument, the government argued that the facts of this case were similar to those analyzed and invoked in *Odessa Union*. While *Odessa Union*'s reasoning remains instructive – it is cited throughout this opinion - the factual comparisons are better suited for the more typical adulteration case involving contaminated food and insanitary working conditions. The circumstances here are distinguishable from *Odessa Union*, where FDA inspections revealed that the wheat in the Odessa-operated elevators was moldy and contaminated with live and dead insects, insect larvae and rodent excreta. *See Odessa Union*, 833 F.2d at 174 ("In May 1985, [FDA] inspections showed live insect infestation at each of seven facilities [...] [t]wo stations contained rodent excreta on the grain-conveying equipment. In 1983

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[10] A food is deemed adulterated under 21 U.S.C. § 342(a)(4) if "processed under insanitary conditions, whether [the food has] actually ... become dangerous to health or not." *Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d at 44. To prove adulteration under § 342(a)(4), the government must show a "reasonable possibility" that, by virtue of the insanitary conditions under which the food is prepared, packed, or held, an article of food may have been rendered filthy or injurious to health. *Id.*

and 1984, the Washington State Department of Agriculture [...] inspected Odessa's storage facilities and discovered significant sanitary problems [...] [a]s a result of the [] inspections, the government sought a preliminary injunction to enjoin the sale and movement of wheat held in Odessa's elevators until Odessa complied with FDCA standards.").

The same reasoning applies to the remaining "adulterated food" cases cited in the government's motion, *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30 (E.D.N.Y. 2001) and *United States v. Union Cheese Co.*, 902 F. Supp. 778 (N.D. Ohio 1995). In those cases, defendants were enjoined on grounds that their operating plants were "insanitary" and they "distributed adulterated []food on a continued basis throughout the years." Specifically, in *Blue Ribbon Smoked Fish,* FDA inspections revealed old seafood product residue on food contact surfaces; mold in the cooler, freezer, and ceiling of the slicing and packing room; a plastic dividing curtain that touched the floor and came into contact with fish; liquid dripping onto seafood from other seafood stored above; and old dripping product residue on the walls and fan shrouds in the cold smoking/drying room.[11] *Id.* at 36-37. FDA inspections at the plant also revealed the presence of L. monocytogenes, a foodborne pathogen, in food samples and in the plant environment. *Id.* at 46. As in *Odessa Union*, the facts and

[11] The FDA also found that the plant's construction was not designed to prevent bacterial contamination and filth and that there were inadequate doors or barriers between the slicing and packing room and the garage and toilet, lack of control over foot traffic and product flow to prevent cross-contamination of the finished ready-to-eat product and that surfaces were in disrepair making adequate cleaning impossible. *Id.* at 36-37.

reasoning of *Blue Ribbon Smoked Fish* involved contaminated food and unhealthy working conditions, circumstances not present in this case.[12]

In this context, the true defect in the government's proposed injunction comes to light: the injunction mirrors those issued in *Odessa Union* and *Blue Ribbon Smoked Fish*, however, there is no evidence that Defendants' products are adulterated, contaminated, or that they are causing harm to the public.[13] **This is not a 21 U.S.C. § 342 case. Instead, the government's evidence is that Defendants mislabeled, misbranded, and shipped raw milk and raw milk products across state lines in violation of the FDCA. Under well-established precedent, injunctive relief must be narrowly-tailored to reflect that evidence and prevent specific harms threatened. On these facts, the suggestion that government should have the access and control normally associated with contamination/adulteration cases is unpersuasive.**

The distinction between this case and those involving

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[12] At oral argument, counsel for the United States stated: "[T]he FDA has not conducted an inspection of the facility to ascertain their compliance with the [FDCA] and the [PHSA]." This fact alone distinguishes this case from *Odessa Union* and *Blue Ribbon Smoked Fish.*

[13] Paragraph 14 of the government's proposed injunction is instructive: "Duly authorized representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary *to make inspections of Defendants' facilities* [...] FDA representatives shall be permitted prompt access to buildings, equipment, in-process and finished materials, containers, labeling, and other material therein; to take photographs and make video recordings; *to take samples of Defendants' finished and unfinished materials and products* [....]". (Doc. 22-4, ¶ 14) (emphasis added). The record in this case does not support such expansive injunctive relief. This is not a 21 U.S.C. § 342 case.

contamination, such as *Odessa Union* and *Blue Ribbon Smoked Fish*, was developed in detail in open court during oral argument. In reference to the FDA's ability to inspect Organic Pastures' facilities without prior notice, which the government requested in paragraph 14 of the proposed injunction, the Court stated:

> **[Paragraph 14 states that] [d]uly authorized representatives shall be permitted without prior notice and as and when FDA deems necessary to make an inspection of their facilities, et cetera, et cetera, et cetera.**
>
> **And again, if this were a dirty operator, if you had found conditions in the plant that would cause you to distrust their operations, their sanitation practices, the integrity of the products, this might be justified. But there's no evidence that the defendants' products are adulterated or contaminated or that they are causing harm to the public. And again, the law is very clear[] on injunctive relief. The injunctive relief should be no broader than is necessary to accomplish the purposes for which it is sought.**
>
> **And here, you're -- it seems to me like you're mixing apples and oranges. You're taking language from orders where you have contamination, where you've had adulteration, where you've had other kinds of risks rather than -- this is simply, if you will, mislabeling, referring to something as a drug, having beneficial effects, and the third thing is you want to prohibit interstate sales. And these kinds of inspections and these kinds of, if you will, access to buildings and the like, without a search warrant seem to me there's no facts whatsoever to justify them. If you want a records inspection provision, to inspect sales records, to inspect invoices, that's something entirely different, That would be consistent with what you're seeking here. But, in other words, here you're asking for remedies for which there's no evidence whatsoever to support.**

(RT, March 12, 2010, 33:23-34:25.)

Here, the government has demonstrated that Defendants violated 21 U.S.C. § 331(a) and (d), which prohibit distributing raw milk across state lines and marketing raw milk's health benefits. The

government has also established a likelihood of additional FDCA violations under Ninth Circuit precedent. Therefore, the Government's motion for summary judgment is GRANTED and Defendants shall be permanently enjoined from such distribution. The government's proposed injunction, however, is not narrowly-tailored to the evidence and is more suited for a contamination/adulteration case such as *Odessa Union* and *Blue Ribbon Smoked Fish*. The terms of the permanent injunction must comport with principles of equity and be "in harmony with the overall objectives of the legislation [the FDCA]." *Commodity Futures Trading Comm'n v. Hunt*, 591 F.2d 1211, 1219 (7th Cir. 1979). The Court has fashioned the permanent injunction accordingly.

VI. CONCLUSION

For the foregoing reasons:

1. The government's motion for summary judgment is GRANTED.

2. Defendants Organic Pastures Dairy Company and Mark McAfee are hereby enjoined from violating 21 U.S.C. § 331(a) and (d) as follows:

A. Defendants and their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them must not introduce or deliver for introduction into interstate commerce any food that is misbranded under 21 U.S.C. § 343(a);

B. Defendants and their directors, officers, agents,

representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them must not introduce or deliver for introduction into interstate commerce any "unapproved new drugs" within the meaning of 21 U.S.C. § 321(p);

C. Defendants and their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them must not introduce or deliver for introduction into interstate commerce raw milk or raw milk products in final package form within the meaning of 42 U.S.C. § 264(a);

D. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from directly and indirectly introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce any raw milk and raw milk products as defined at 21 C.F.R. § 1240.3(I) and (j), including any products that contain raw milk and/or raw colostrum, in any form (e.g., frozen, partially-frozen, liquid, dry, powdered) for any intended use (e.g., human consumption, pet food, and any other use) regardless of how labeled, described, represented or designated, unless specifically authorized in writing by the FDA in advance of any such introduction or delivery for introduction into

interstate commerce. If the FDCA is amended or modified to allow the interstate sale of raw milk or raw milk products, advanced FDA approval is not necessary and this order is amended accordingly without the necessity for further Court action.

E. Defendants shall maintain records regarding the sale and/or distribution of all of Defendants' raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum) including, but not limited to, records demonstrating to whom (name and address) products were sold and distributed, the date of sale and distribution, and the product type and amount/quantity. Defendants shall also maintain at least one copy of the following documentation with respect to their raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum): (a) all label(s) affixed to the products; (b) all stickers and labeling affixed to shipping containers; and (c) all flyers, brochures, labeling, and other materials promoting, describing, or otherwise relating to these products. Upon request, FDA shall have prompt access to all of the records and/or documents described herein.

F. Upon entry of this Order, Defendants shall add the following statement to the individual retail invoices and packaging slips for each of Defendants' raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum): "Organic Pastures will no longer offer for introduction, introduce, or cause to be introduced into interstate commerce, or deliver or cause to be delivered for introduction into

interstate commerce, any unpasteurized raw milk or raw milk products." Upon entry of this Order, Defendants shall also post this written statement on all websites that Defendants own or control and on all websites on which Defendants make available for purchase (either via a hyperlink or reference to another website) its raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum), including but not limited to www.organicpastures.com. This statement shall be continuously displayed on each websites' home page and on each page from which Defendants' products can be ordered through their website(s), by mail, or by telephone. Upon entry of this Order, Defendants shall also remove from their corporate vehicle or other locations it is displayed, any reference to raw milk as a cure for asthma or any statement/slogan promoting raw milk's health benefits.

G. Upon entry of this Order, Defendants shall provide notice to its commercial buyers, defined as those persons or entities purchasing in excess of 2% of Defendants' gross sales from raw milk/raw milk products (combined on a yearly basis), or for wholesale and/or retail redistribution, that its raw milk and raw milk products are not to be sold or distributed outside the state of California. Such notice can be accomplished by adding such a statement to the commercial retail invoices and packaging slips, obtaining a signed written statement from the person or entity, or sending a notarized letter to the appropriate mailing address (person's place of business or entity's headquarters). Defendants shall maintain copies of the selected method of notification and shall make them immediately available to FDA upon request. If the

FDCA is amended or modified to allow the interstate sale of raw milk or raw milk products, this provision shall no longer have effect.

H. Within ten (10) calendar days after the entry of this Order, Defendants shall provide a duly executed copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, retail/wholesale consignees of their raw milk and raw milk products (including any products that contain raw milk and/or raw colostrum), successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including "doing business as" entities). Within thirty-five (35) calendar days of the date of entry of this Order, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all associated persons who have received a copy of this Order and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Order, with new associated persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Order to each such associated person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Order was provided.

I. Within ten (10) calendar days of entry of this Order,

Defendants shall post a copy of this Order in a conspicuous location in a common area at any of their manufacturing or distribution facilities, and shall ensure that the Order remains posted for a period of twelve (12) months at each location.

J. Defendants shall notify the District Director, FDA San Francisco Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the corporate structure of Organic Pastures, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

K. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Order shall be addressed to the Director, FDA San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California, 94502-7070.

L. This order does not in any way limit the FDA's ability

under generally applicable federal laws and regulations to regulate, monitor, inspect, and supervise Organic Pastures Dairy Company or any business operated, directly or indirectly, by Mark McAfee. This order also does not in any way relieve Organic Pastures Dairy Company or Mark McAfee of their obligations to comply with generally applicable federal laws and regulations.

M. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

N. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to enforce or modify this Order and for granting such other relief as may be necessary and appropriate for the proper disposition of this case.

IT IS SO ORDERED.

Dated: April 20, 2010 **/s/ Oliver W. Wanger**
UNITED STATES DISTRICT JUDGE