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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

1:08-CV-01786-OWW-GSA

Plaintiff,

MEMORANDUM DECISION AND ORDER
RE: UNITED STATES OF AMERICA'S
MOTION FOR SUMMARY JUDGMENT
(Doc. 22.)

v.

ORGANIC PASTURES DAIRY
COMPANY, *et al.*,

Defendants.

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.

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

10
11 **II. FACTUAL BACKGROUND**

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

15
16 **A. The Parties**

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

22
23 ¹ Unless otherwise noted, the facts are undisputed. (See
24 Stmt. of Undisp. Facts in Support of Def.'s Mot. for Summ. J.
25 ("SUF"), filed by the United States on Dec. 8, 2009). Defendants
26 object to much of the evidence submitted by the United States on
27 various grounds. Virtually all of Defendants' objections are
28 without merit. To the extent that Defendants' sole dispute with
facts is based upon the inadmissibility of the government's
evidence, and is not challenged by any admissible evidence
submitted by Defendants, these facts are viewed as undisputed.

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

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

9
10 **B. Defendants' Interstate Raw Milk Practices**

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

20 On October 10, 2007, one or more of defendant Organic
21 Pastures' agents or employees, with the knowledge and
22 consent of Organic Pastures, caused a box of raw milk
23 and dairy products, labeled as or otherwise
24 represented to be "pet food," to be sent by defendant
25 Organic Pastures from Fresno, California to Renton,
26 Washington, knowing that the intended use of such
27 foods and/or dietary supplements was for human
28 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.

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

1 represented to be "pet food," to be sent by defendant
2 Organic Pastures from Fresno, California to Reno,
3 Nevada, knowing that the intended use of such foods
4 and/or dietary supplements was for human consumption.
5 The box contained one ½ gallon of unpasteurized raw
6 whole milk and one pint of unpasteurized raw
7 colostrum. The invoice number was #165465524.

8 These products were foods and/or dietary supplements,
9 and were misbranded when so introduced into or
10 delivered for introduction into interstate commerce,
11 in that they were falsely and misleadingly labeled as,
12 or otherwise represented to be "pet food," when they
13 were actually intended for human consumption, in
14 violation of Title 21, United States Code, Sections
15 331(a) and 333(a) (1).

16 (Doc. 24-14, Defendant McAfee's "Deferred Prosecution Agreement,"
17 at 9:3-9:23.²)

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

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

27 ³ The relevant shipping containers were for products sold in
28 interstate commerce in 2007.

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

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

15 (SUF 18.)

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

27 The United States identifies another email, this one sent by
28 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."

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

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

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

15 (SUF 55.)

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

25 According to the United States, Defendants' employees have
26 also made statements reflecting Organic Pastures' intention to sell
27 raw milk in interstate commerce. In July 2005, an FDA investigator
28 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.)

1 The Organic Pastures sales representative responded that the
2 product was safe for humans and that the "'pets only' sticker is a
3 legal loophole for us to sell out of state." (Id.)
4

5 C. Related Criminal Proceeding

6 While this case was pending, Defendant Organic Pastures faced
7 similar charges in a criminal action involving similar conduct.
8 The criminal matter concluded in settlement by plea agreement on
9 December 22, 2008 and was approved by Magistrate Judge Sandra M.
10 Snyder on January 9, 2009. (SUF 69.) Pursuant to the plea
11 agreement, Defendant Organic Pastures pled guilty to two counts of
12 misdemeanor introduction and delivery for introduction into
13 interstate commerce of misbranded food, in violation of 21 U.S.C.
14 §§ 331(a) and 333(a)(1). (SUF 70.) Defendant McAfee entered into
15 a deferred prosecution agreement whereby he agreed to the filing of
16 a two count information charging him and Organic Pastures with the
17 same violations. (SUF 71.)

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

1 misleadingly labeled as, or otherwise represented to be 'pet food,'
2 when they were actually intended for human consumption in violation
3 of [21 U.S.C. §§ 331(a) and 333(a)(1).]" (SUF 72-73.)
4

5 III. PROCEDURAL BACKGROUND

6 On November 20, 2008, the United States filed a civil
7 complaint for permanent injunction, alleging that Defendants
8 violated: (1) 21 U.S.C. § 331(a), by introducing or delivering,
9 and causing to be introduced or delivered, into interstate commerce
10 food that is misbranded within the meaning of 21 U.S.C. §
11 343(a)(1); (2) the Public Health Services Act ("PHSA"), 42 U.S.C.
12 § 264, by distributing raw milk and raw milk products in interstate
13 commerce in final package form for human consumption; and (3) 21
14 U.S.C. § 331(d), by introducing or delivering, and causing to be
15 introduced or delivered, into interstate commerce new drugs within
16 the meaning of 21 U.S.C. § 321(p) that are neither approved under
17 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C.
18 § 355(I). (Doc. 1.)

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

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

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

3 Defendants opposed the United States' motion on January 19,
4 2010. (Doc. 31.) In support of its opposition, Defendants
5 submitted: (1) a Memorandum opposing the motion ("Opposition"); (2)
6 the Declaration of Mark McAfee; (3) the Declaration of J. Kenneth
7 Gorman; and (4) a Request for Judicial Notice.⁴ (Docs. 33 through
8 36.)

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

18 19 IV. LEGAL STANDARD

20 Summary judgment/adjudication is appropriate when "the
21 pleadings, the discovery and disclosure materials on file, and any
22 affidavits show that there is no genuine issue as to any material
23 fact and that the movant is entitled to judgment as a matter of
24 law." Fed. R. Civ. P. 56©. The movant "always bears the initial
25

26
27 ⁴ Defendants request judicial notice of California Food and
28 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.

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

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

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

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

8
9 V. DISCUSSION

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

19 Defendants do not dispute the liability portions of the United
20 States' motion. In particular, Defendants acknowledge that they
21 introduced and/or distributed raw milk into interstate commerce in
22 2007 in violation of 21 U.S.C. § 331(a) and 42 U.S.C. § 264(a).
23 (See Doc. 31, 4:19-4:20 ("[Defendants] do[] not dispute that the
24 deferred prosecution agreement and plea agreement bar any argument
25

26 ⁵ The government provides a "Proposed Order of Permanent
27 Injunctive Relief," outlining the proposed terms for injunctive
28 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.

1 [on] liability on the charges of mislabeling its conduct
2 [....]"⁶ Nor do Defendants oppose the government's "unapproved
3 new drugs" claim, which was advanced pursuant to 21 U.S.C. §
4 331(d).⁷ Defendants do, however, object to the breadth of the
5 government's proposed injunction.

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

18 ⁶ According to Defendants, although "the plea agreements
19 establish liability as a matter of law, they do not establish the
20 penalty as a matter of law, and the drastic remedies sought by the
21 Federal government are not warranted in any respect." (Doc. 31,
22 5:16-5:18.)

23 ⁷ In opposing the United States' motion for summary judgment,
24 Defendants initially argue that the government did not "present any
25 evidence that any consumer purchased raw milk with the expectation
26 that it was a 'drug.'" Defendants also challenge the evidentiary
27 basis to elevate raw milk to "drug" status. Defendants, however,
28 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.

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

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

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

24
25 ⁸ The probability of future violations may also be inferred
26 based on Defendants' numerous statements of intent to ignore and
27 violate the prohibition against interstate raw milk sales. *Id.*
28 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.

1 Organic Pastures' website all claims/testimonials concerning raw
2 milk's health benefits. Although Defendants' progress towards
3 improvement and their intention to comply with FDCA requirements
4 are relevant to the inquiry, the Ninth Circuit has emphasized that
5 a past pattern of activity bears heavily on whether the offender is
6 likely to violate the FDCA in the future. See *Odessa Union*, 833
7 F.2d at 176 ("the district court must weigh [the offender's]
8 continuing [] problems in light of its extensive history of
9 violations, since an inference arises from [the offender's] past
10 violations that future violations are likely to occur."). Courts
11 have also recognized the carry-over effects of marketing and
12 promotional claims in actions arising under the FDCA. See *United*
13 *States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 574 (D.N.J.
14 2004).

15 Here, given the history of admitted violations by Defendants,
16 as well as their acknowledgments concerning the promotion of raw
17 milk's therapeutic effects, the government has established a
18 likelihood of additional FDCA violations. *Odessa Union*, 833 F.2d
19 at 176; see also *Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 574-76
20 (finding that likelihood of continuing FDCA violations was "great"
21 despite the company's arguments that it had not violated the FDCA
22 for many years.⁹). Given the uncontested facts, Defendants cannot
23

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

Defendants further contend that they have rectified

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

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

15 any past missteps [...] Defendants claim that they
16 have cooperated with the FDA in every regard by
17 complying with FDA inspections, permitting access to
18 Lane Labs' facilities and supplying records and
19 materials requested by the Government. Defendants
20 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 [...]

21 However, Defendants' past pattern of activity bears
22 upon whether Lane Labs is likely to violate the FDCA
23 in the future. Courts have recognized the carry-over
24 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 [...]

25 Given Defendants' past pattern of behavior, in which
26 Lane Labs has purposefully flouted the FDCA framework
27 throughout the pendency of this lawsuit, this Court
finds that an injunction of this scope is warranted.

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

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

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

14 The government responds that the proposed injunction in the
15 case is no different than the injunctions in *Odessa Union*, 833 F.2d
16 172, *Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, and *United States v.*
17 *Endotec, Inc.*, 06-CV-1281-ORL-18KRS, 2009 WL 3111815 (M.D. Fla.
18 Sep. 28, 2009). Specifically, the government argues that the
19 proposed injunctive relief is "both warranted and necessary to
20 ensure that Defendants do not resume their unlawful conduct." As
21 to FDA involvement, the government offers a similar take: the terms
22 are "essential to enable the FDA to ensure [] compliance with the
23 FDCA, the PHSA, and the regulations."

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

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

10 Court: Paragraph 11 [...] calls for the obtaining of
11 written statements from any purchaser or a
12 reseller that the person or entity will not sell
13 outside the State of California and the
14 defendants are required to maintain copies of
15 the signed statements and make them immediately
16 available to the FDA on request.

17 The Court has the concern that this paragraph
18 does not say interstate. Conceivably, one way
19 to read this paragraph is that every carton of
20 milk that's sold or any raw milk product that is
21 sold is going to require the consumer and the
22 retailer and/or wholesaler to sign this
23 statement. And that would, I think, have such
24 a chilling effect on the conduct of business
25 that it would put the defendant out of business.
26 And because it says to any person or entity that
27 purchases these products and holds these
28 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.

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

1 many, if you will, resellers they sell to, But
2 the Court can certainly conceive that this isn't
3 just, for instance, grocery stores or other
4 distributors who have large customer bases.
5 This applies to anybody and everybody who's
6 going to resell milk.

7
8 Counsel: And Your Honor, you did -- I think the operative
9 language in here is that it applies to entities
10 that hold products for resale.

11 Court: Right.

12 Counsel: I think the FDA -- the government would be
13 remiss in not including this paragraph to
14 prevent the scenario where, you now, straw
15 purchasers are middle men who are not named in
16 the order and have no notice of the order can
17 participate in a chain transaction that will
18 milk or other raw milk products across [...]

19 Court: Well, for instance, is there one iota of
20 evidence that the defendant has ever done this?

21 Counsel: Your Honor, the defendant's wrote [...] that
22 their employees had knowledge that milk had been
23 sold to people who were intending to take milk
24 across state lines [...] the reason we are
25 asking for written statements for people that
26 are going to resell [raw milk] is that those
27 people, who are taking milk across state lines,
28 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 the people they know
are reselling this milk [...]

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.

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

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

9 This case differs from those involving "adulterated food"
10 under 21 U.S.C. § 331(a) and § 21 U.S.C. § 342.¹⁰ At oral argument,
11 the government argued that the facts of this case were similar to
12 those analyzed and invoked in *Odessa Union*. While *Odessa Union's*
13 reasoning remains instructive - it is cited throughout this opinion
14 - the factual comparisons are better suited for the more typical
15 adulteration case involving contaminated food and insanitary
16 working conditions. The circumstances here are distinguishable
17 from *Odessa Union*, where FDA inspections revealed that the wheat in
18 the *Odessa*-operated elevators was moldy and contaminated with live
19 and dead insects, insect larvae and rodent excreta. See *Odessa*
20 *Union*, 833 F.2d at 174 ("In May 1985, [FDA] inspections showed live
21 insect infestation at each of seven facilities [...] [t]wo stations
22 contained rodent excreta on the grain-conveying equipment. In 1983

24 ¹⁰ A food is deemed adulterated under 21 U.S.C. § 342(a)(4) if
25 "processed under insanitary conditions, whether [the food has]
26 actually ... become dangerous to health or not." *Blue Ribbon*
27 *Smoked Fish, Inc.*, 179 F. Supp. 2d at 44. To prove adulteration
28 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.*

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

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

24
25 ¹¹ The FDA also found that the plant's construction was not
26 designed to prevent bacterial contamination and filth and that
27 there were inadequate doors or barriers between the slicing and
28 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.

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

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

17 The distinction between this case and those involving
18

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

24 ¹³ Paragraph 14 of the government's proposed injunction is
25 instructive: "Duly authorized representatives of FDA shall be
26 permitted, without prior notice and as and when FDA deems necessary
27 to make inspections of Defendants' facilities [...] FDA
28 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.

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

6 [Paragraph 14 states that] [d]uly authorized
7 representatives shall be permitted without prior
8 notice and as and when FDA deems necessary to make an
inspection of their facilities, et cetera, et cetera,

9 And again, if this were a dirty operator, if you had
10 found conditions in the plant that would cause you to
11 distrust their operations, their sanitation practices,
12 the integrity of the products, this might be
13 justified. But there's no evidence that the
14 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.

15 And here, you're -- it seems to me like you're mixing
16 apples and oranges. You're taking language from
17 orders where you have contamination, where you've had
18 adulteration, where you've had other kinds of risks
19 rather than -- this is simply, if you will,
20 mislabeling, referring to something as a drug, having
21 beneficial effects, and the third thing is you want to
22 prohibit interstate sales. And these kinds of
23 inspections and these kinds of, if you will, access to
24 buildings and the like, without a search warrant seem
25 to me there's no facts whatsoever to justify them. If
26 you want a records inspection provision, to inspect
27 sales records, to inspect invoices, that's something
28 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

1 government has also established a likelihood of additional FDCA
2 violations under Ninth Circuit precedent. Therefore, the
3 Government's motion for summary judgment is GRANTED and Defendants
4 shall be permanently enjoined from such distribution. The
5 government's proposed injunction, however, is not narrowly-tailored
6 to the evidence and is more suited for a contamination/adulteration
7 case such as *Odessa Union* and *Blue Ribbon Smoked Fish*. The terms
8 of the permanent injunction must comport with principles of equity
9 and be "in harmony with the overall objectives of the legislation
10 [the FDCA]." *Commodity Futures Trading Comm'n v. Hunt*, 591 F.2d
11 1211, 1219 (7th Cir. 1979). The Court has fashioned the permanent
12 injunction accordingly.

13
14 VI. CONCLUSION

15 For the foregoing reasons:

- 16 1. The government's motion for summary judgment is GRANTED.
17
18 2. Defendants Organic Pastures Dairy Company and Mark McAfee are
19 hereby enjoined from violating 21 U.S.C. § 331(a) and (d) as
20 follows:

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

27
28 B. Defendants and their directors, officers, agents,

1 representatives, employees, attorneys, successors, assigns, and any
2 and all persons in active concert or participation with them must
3 not introduce or deliver for introduction into interstate commerce
4 any "unapproved new drugs" within the meaning of 21 U.S.C. §
5 321(p);

6
7 C. Defendants and their directors, officers, agents,
8 representatives, employees, attorneys, successors, assigns, and any
9 and all persons in active concert or participation with them must
10 not introduce or deliver for introduction into interstate commerce
11 raw milk or raw milk products in final package form within the
12 meaning of 42 U.S.C. § 264(a);

13
14 D. Upon entry of this Order, Defendants and each and all of
15 their directors, officers, agents, representatives, employees,
16 attorneys, successors, assigns, and any and all persons in active
17 concert or participation with any of them who receive actual notice
18 of this Order by personal service or otherwise, are permanently
19 restrained and enjoined from directly and indirectly introducing
20 and delivering for introduction, and causing to be introduced and
21 delivered for introduction, into interstate commerce any raw milk
22 and raw milk products as defined at 21 C.F.R. § 1240.3(I) and (j),
23 including any products that contain raw milk and/or raw colostrum,
24 in any form (e.g., frozen, partially-frozen, liquid, dry, powdered)
25 for any intended use (e.g., human consumption, pet food, and any
26 other use) regardless of how labeled, described, represented or
27 designated, unless specifically authorized in writing by the FDA in
28 advance of any such introduction or delivery for introduction into

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

5
6 E. Defendants shall maintain records regarding the sale
7 and/or distribution of all of Defendants' raw milk and raw milk
8 products (including any products that contain raw milk and/or raw
9 colostrum) including, but not limited to, records demonstrating to
10 whom (name and address) products were sold and distributed, the
11 date of sale and distribution, and the product type and
12 amount/quantity. Defendants shall also maintain at least one copy
13 of the following documentation with respect to their raw milk and
14 raw milk products (including any products that contain raw milk
15 and/or raw colostrum): (a) all label(s) affixed to the products;
16 (b) all stickers and labeling affixed to shipping containers; and
17 (c) all flyers, brochures, labeling, and other materials promoting,
18 describing, or otherwise relating to these products. Upon request,
19 FDA shall have prompt access to all of the records and/or documents
20 described herein.

21
22 F. Upon entry of this Order, Defendants shall add the
23 following statement to the individual retail invoices and packaging
24 slips for each of Defendants' raw milk and raw milk products
25 (including any products that contain raw milk and/or raw
26 colostrum): "Organic Pastures will no longer offer for
27 introduction, introduce, or cause to be introduced into interstate
28 commerce, or deliver or cause to be delivered for introduction into

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

15
16 G. Upon entry of this Order, Defendants shall provide notice
17 to its commercial buyers, defined as those persons or entities
18 purchasing in excess of 2% of Defendants' gross sales from raw
19 milk/raw milk products (combined on a yearly basis), or for
20 wholesale and/or retail redistribution, that its raw milk and raw
21 milk products are not to be sold or distributed outside the state
22 of California. Such notice can be accomplished by adding such a
23 statement to the commercial retail invoices and packaging slips,
24 obtaining a signed written statement from the person or entity, or
25 sending a notarized letter to the appropriate mailing address
26 (person's place of business or entity's headquarters). Defendants
27 shall maintain copies of the selected method of notification and
28 shall make them immediately available to FDA upon request. If the

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

4
5 H. Within ten (10) calendar days after the entry of this
6 Order, Defendants shall provide a duly executed copy of this Order,
7 by personal service or certified mail (restricted delivery, return
8 receipt requested), to each and all of its directors, officers,
9 agents, representatives, employees, retail/wholesale consignees of
10 their raw milk and raw milk products (including any products that
11 contain raw milk and/or raw colostrum), successors, assigns,
12 attorneys, and any and all persons in active concert or
13 participation with any of them (including "doing business as"
14 entities). Within thirty-five (35) calendar days of the date of
15 entry of this Order, Defendants shall provide to FDA an affidavit
16 of compliance, stating the fact and manner of compliance with the
17 provisions of this paragraph and identifying the names and
18 positions of all associated persons who have received a copy of
19 this Order and the manner of notification. In the event that
20 Defendants become associated, at any time after the entry of this
21 Order, with new associated persons, Defendants shall: (a) within
22 fifteen (15) calendar days of such association, provide a copy of
23 this Order to each such associated person by personal service or
24 certified mail (restricted delivery, return receipt requested), and
25 (b) on a quarterly basis, notify FDA in writing when, how, and to
26 whom the Order was provided.

27
28 I. Within ten (10) calendar days of entry of this Order,

1 Defendants shall post a copy of this Order in a conspicuous
2 location in a common area at any of their manufacturing or
3 distribution facilities, and shall ensure that the Order remains
4 posted for a period of twelve (12) months at each location.
5

6 J. Defendants shall notify the District Director, FDA San
7 Francisco Office, in writing at least fifteen (15) calendar days
8 before any change in ownership, character, or name of its business,
9 such as dissolution, assignment, or sale resulting in the emergence
10 of a successor corporation, the creation or dissolution of
11 subsidiaries, franchises, affiliates, or "doing business as"
12 entities, or any other change in the corporate structure of Organic
13 Pastures, or in the sale or assignment of any business assets, such
14 as buildings, equipment, or inventory, that may affect compliance
15 with this Order. Defendants shall provide a copy of this Order to
16 any potential successor or assignee at least fifteen (15) calendar
17 days before any sale or assignment. Defendants shall furnish FDA
18 with an affidavit of compliance with this paragraph no later than
19 ten (10) calendar days prior to such assignment or change in
20 ownership.
21

22 K. All notifications, certifications, reports,
23 correspondence, and other communications to FDA required by this
24 Order shall be addressed to the Director, FDA San Francisco
25 District Office, 1431 Harbor Bay Parkway, Alameda, California,
26 94502-7070.
27

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

1 under generally applicable federal laws and regulations to
2 regulate, monitor, inspect, and supervise Organic Pastures Dairy
3 Company or any business operated, directly or indirectly, by Mark
4 McAfee. This order also does not in any way relieve Organic
5 Pastures Dairy Company or Mark McAfee of their obligations to
6 comply with generally applicable federal laws and regulations.
7

8 M. Should the United States bring and prevail in a contempt
9 action to enforce the terms of this Order, Defendants shall, in
10 addition to other remedies, reimburse the United States for its
11 attorneys' fees, court costs, expert witness fees, and
12 investigational and analytical expenses incurred in bringing such
13 an action.
14

15 N. This Court retains jurisdiction to issue such further
16 decrees and orders as may be necessary to enforce or modify this
17 Order and for granting such other relief as may be necessary and
18 appropriate for the proper disposition of this case.
19

20 IT IS SO ORDERED.

21 Dated: April 20, 2010

/s/ Oliver W. Wanger
UNITED STATES DISTRICT JUDGE