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

Farm-to-Consumer Legal Defense Fund, et al.	:	**Case No. 5:10-cv-4018**
Plaintiffs	:	**Judge Mark W. Bennett**
v.	:	
Sebelius, et al.	:	**AFFIDAVIT OF PETER KENNEDY**
Defendants	:	

STATE OF FLORIDA :
COUNTY OF SARASOTA :

I, Peter Kennedy, being under oath, do hereby make the following statements based on my personal knowledge, understanding and belief.

1. I reside at 8026 Midnight Pass Road, Sarasota, Florida.
2. I am an attorney licensed to practice law in the State of Florida and have been so licensed since 1985.
3. I am currently the President of the Plaintiff Farm-to-Consumer Legal Defense Fund ("the Fund") and have been President since 2008.
4. I am also a Board member of the Fund and have been a Board member since July 2007.
5. In my capacity as Board member of the Fund, I have provided legal counsel to the Fund's members since its inception in July 2007.
6. As President of the FTCLDF, I am familiar with and have personal knowledge of the Plaintiffs, legal issues, facts, and pleadings filed in this case.
7. Having worked on raw milk issues since 2004, I am familiar with and have personal knowledge of the general position of the U.S. Food and Drug Administration (FDA) on raw milk.
8. As part of my duties as attorney for the Fund, I counseled Michael and Anita Puckett, owners and operators of Dee Creek Farm, a dairy farm located in the State of Washington.

9. From 2007 to 2008, the Pucketts were the subject of a criminal investigation conducted by FDA's Office of Criminal Investigations and were, at that time, members of the Farm-to-Consumer Legal Defense Fund.

10. The FDA criminal investigation looked into whether the Puckett's were engaged in the interstate distribution of raw milk and/or raw dairy products.

11. The FDA criminal investigation concluded that the Pucketts knew that residents of the State of Oregon had traveled to Washington to obtain raw milk from the Pucketts and that the Oregon residents had taken that raw milk back across state lines into Oregon for human consumption.

12. The FDA criminal investigation concluded that the Pucketts were in violation of 21 C.F.R. 1240.61.

13. On May 2, 2006, FDA sent a warning letter to the Pucketts, claiming that their dairy farm "caused to be delivered into interstate commerce unpasteurized milk, in finished form for human consumption" and that such distribution "is a violation of the Public Health Service Act (PHS Act), 42 U.S.C. Section 271(a), and the regulation codified in title 21, Code of Federal Regulations (CFR), section 1240.61(a)." See Attachment A attached hereto.

14. In 2008, the United States Attorney Office for the Western District of Washington brought a criminal complaint against the Pucketts and charged them with distributing adulterated food in interstate commerce.

15. In 2008, the Pucketts pled guilty and sentencing was imposed by Magistrate Karen Strombom in October 2008 in Case No. 3:08-cr-05424.

16. Based on my dealings with FDA in the Pucketts' and Dee Creek case, it is FDA's interpretation and application of the law that a farmer who makes raw milk and/or raw dairy products available for distribution across state lines when those products are in final package form and are intended for human consumption is in violation of 21 C.F.R. 1240.61 and 21 C.F.R 131.110 and is subject to criminal prosecution.

17. As an attorney for the Fund, I have also been involved in other instances where members of the Fund have been the target of FDA enforcement actions for allegedly violating 21 C.F.R. 1240.61.

18. For example, I am aware that a South Carolina dairy farmer has received a warning letter from FDA, claiming that he has been illegally distributing raw

milk and/or raw dairy products across state lines in violation of 21 C.F.R. 1240.61.

19. Specifically, even though he never left the state, the South Carolina farmer's raw dairy products were being purchased by out-of-state residents and taken across state lines to their state of residence.

20. Like the Pucketts, this South Carolina farmer also received a warning letter from FDA, alleging that the farmer was "causing to be delivered, selling, or otherwise distributing raw milk, in final package form for human consumption, in interstate commerce. Such distribution is a violation of the Public Health Service Act (PHS Act), 42 U.S.C. §§ 264(a) and 271(a), and the implementing regulation codified in Title 21, Code of Federal Regulations (CFR), section 1240.61(a)." See Attachment B attached hereto.

21. I certify that Attachments A and B are copies of the original and have not been materially altered in any way. I also certify that Attachments A and B are in a file over which I have custody and that Attachments A and B were sent by the FDA as documents that were generated in the ordinary course of business of the FDA.

22. In each of these actions, FDA took the position that the farmer was distributing raw milk and/or raw dairy products in final package form intended for human consumption across state lines in violation of 21 C.F.R. 1240.61, even though the farmer himself never crossed state lines.

23. FDA is totally opposed to the distribution and consumption of raw milk.

24. In testimony submitted at a March 17, 2007 hearing before the Maryland House of Delegates, Health and Government Operations Committee, John F. Sheehan as the Director of the Division of Plant and Dairy Food Safety for FDA in the Center for Food Safety and Applied Nutrition (CFSAN) stated, "Raw milk should not be consumed by anyone, at any time, for any reason."

25. In the September/October 2004 issue of *FDA Consumer*, Mr. Sheehan was quoted in an article titled, "Got Milk? Make Sure It's Pasteurized", saying, "Drinking raw milk or eating raw milk products is like playing Russian roulette with your health." This statement has been repeated by other FDA officials and can be found on its website.

26. At the 2005 National Conference on Interstate Milk Shipments, the FDA supported a NCIMS resolution encouraging "states to pass laws or adopt administrative rules that *prohibit* the sale of raw milk directly to the household consumer. . . "

27. FDA's opposition to raw milk is so great that the agency refuses to debate any individual or organization with a different viewpoint.

28. On August 13, 2007, a National Public Radio program on raw milk hosted by Kojo Nnamdi aired. FDA had been invited to participate; but according to Mr. Nnamdi, FDA "declined to designate a representative, saying 'this is not a debatable issue '"

29. On February 17, 2009 in Arlington, Virginia, the International Association for Food Protection held a symposium entitled, "Raw Milk Consumption: An Emerging Public Health Threat". Mr. Sheehan was to be a keynote speaker at the symposium; however, shortly after learning that representatives of the pro-raw milk Weston A. Price Foundation were planning to attend, Sheehan and other FDA officials scheduled to attend withdrew just four days before the symposium was to begin.

30. Based on my personal knowledge of FDA's refusal to debate anyone on the issue of the safety of raw milk; their consistent public statements that raw milk should not be consumed by anyone at anytime; and their refusal to take any action on the citizen's petition filed by California dairy farmer Mark McAfee nearly 18 months ago, I believe it would be futile for Plaintiffs to submit a citizen petition to FDA seeking to amend, revoke or modify 21 C.F.R. 1240.61 and/or 131.110, assuming such a remedy exists for the Plaintiffs in this case.

FURTHER AFFIANT SAYETH NAUGHT

FDA# K530-664-58.326-0
± 9/3/04 & 9/6/10

Peter Kennedy

Sworn and subscribed before me this 14th day of June, 2010.

Notary public

State of Florida
County of Sarasota

MARVIN E HORNBY
MY COMMISSION # DD781418
EXPIRES May 01, 2012
(407) 398-0153 FloridaNotaryService.com

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ATTACHMENT A

Inspections, Compliance, Enforcement, and Criminal Investigations

Dee Creek Farm 02-May-06

Department of Health and Human Services

Public Health Service
Food and Drug
Administration

Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421
Telephone: 425-486-8788
FAX: 425-483-4996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 06-26

Michael E. Puckett and Anita C. Puckett
Dee Creek Farm
P.O. Box 1936
Woodland, WA 98674-1800

WARNING LETTER

Dear Mr and Mrs. Puckett:

An inspection of your dairy operation, located at 2404 Little Kalama River Road, Woodland, Washington, was conducted by representatives of the U.S. Food and Drug Administration (FDA) on December 16, 2005, as part of an investigation of a food borne illness outbreak in Southwest Washington and Northwest Oregon.

Our inspection determined that your dairy farm caused to be delivered into interstate commerce unpasteurized milk, in finished form for human consumption. Such distribution is a violation of the Public Health Service Act (PHS Act), 42 U.S.C. § 271(a), and the regulation codified in Title 21, Code of Federal Regulations (CFR), section 1240.61(a). The regulation bans, among other things, delivering into interstate commerce milk and milk products in final package form for direct human consumption unless they have been pasteurized. Your cow's milk is "milk" as that term is defined by 21 C.F.R. § 131.110. Further, your milk, which you cause to be shipped into interstate commerce is in final package form for direct human consumption. For your information, we have enclosed a copy of the regulation as it was published in the Federal Register, 52 FR 29509 (August 10, 1987).

Additionally, the public health officials of the Oregon Department of Human Services have advised FDA that Dee Creek's unpasteurized milk was responsible for a December 2005 outbreak of E. coli 0157:H7 in Washington and Oregon. The evidence regarding the outbreak shows that your milk contained E. Coli 0157:H7. As such, your unpasteurized milk was adulterated within the meaning of section 402(a)(1), 21 U.S.C. § 342 (a)(1), of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in that the milk contained a poisonous or deleterious substance that rendered it injurious to health.

The above is not intended to be an all-inclusive list of violations. As a producer of food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action, such as a seizure or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your written reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,

/S/

Charles M. Breen
District Director

ATTACHMENT B

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

[redacted]4/20/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District Office
60 8th Street, N E.
Atlanta, Georgia 30309

April 20, 2010

VIA FEDERAL EXPRESS

[redacted], South Carolina [redacted]

WARNING LETTER [redacted]

Dear Mr[redacted]:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your website at the Internet address [redacted] and has determined that you are causing to be delivered, selling, or otherwise distributing raw milk, in final package form for human consumption, in interstate commerce. Such distribution is a violation of the Public Health Service Act (PHS Act), 42 U.S.C. §§ 264(a) and 271(a), and the implementing regulation codified in Title 21, Code of Federal Regulations (CFR), section 1240 61(a). The regulation prohibits the delivery, sale, or distribution in interstate commerce of milk and milk products in final package form for human consumption unless they have been pasteurized

You cause unpasteurized milk, in final package form for human consumption, to be shipped into interstate commerce through raw milk "co-ops." For example, your raw milk is sold through [redacted] in Augusta, GA. For your information, we have enclosed a copy of 21 C F R. § 1240 61 as it was published in the Federal Register, 52 FR 29509 (August 10, 1987).

This letter is not intended to provide an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the PHS Act, the Federal Food, Drug, and Cosmetic Act, and implementing regulations. For instance, you should ensure that your products are properly labeled. You should take prompt action to correct the above deviation and prevent any future recurrence. Failure to make prompt corrections could result in regulatory action without further notice Possible actions include seizure and/or injunction

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed

Please send your written reply to the Food and Drug Administration, Attention: Serene N. Ackall, Compliance Officer at the address noted in the letterhead If you have any questions about this letter, you can call Ms Ackall at 404-253-1296

Sincerely,

/s/

John R Gridley, Director
Atlanta District

Enclosure

Links on this page:

CERTIFICATE OF SERVICE

I hereby certify that June 14 2010, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system that will send notification of such filings(s) to the following:

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/s/ David G. Cox
David G. Cox