

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

FARM-TO-CONSUMER LEGAL)	
DEFENSE FUND, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. C 10-4018-MWB
)	
KATHLEEN SEBELIUS, Secretary,)	
Unites States Department of Health)	
and Human Services, et al.,)	
)	
Defendants.)	

AFFIDAVIT OF STEPHEN BEMIS

STATE OF MICHIGAN :
COUNTY OF WASHTENAW :

Stephen Bemis, being first duly sworn, deposes and gives this Affidavit for the within-described purposes in the above action pending before this honorable Court.

- 1) I am a Member of, and a Founding Board Member and present Board Member of, plaintiff Farm-to-Consumer Legal Defense Fund ("FTCLDF").
- 2) I am an attorney licensed to practice law in the States of Michigan and Illinois (the latter status is "inactive"), and reside at 6500 Jennings Road, Ann Arbor, MI 48105.
- 3) During the period February, 2007 through the end of March, 2010 I represented Farmer Anonymous who is Amish and whose religion prevents him from active participation in litigation including the instant case.
- 4) The representation which I provided to Farmer Anonymous during the referenced period was under the auspices of FTCLDF in which I utilized the assistance of FTCLDF attorneys who continue to practice actively on behalf of FTCLDF and its clients, including its prosecution of the instant case.
- 5) I represented Farmer Anonymous from February, 2007 through the end of March, 2010 against allegations by defendant Food and Drug Administration ("FDA") concerning interstate shipment of raw (unpasteurized) milk in final package form for human consumption allegedly in contravention of the provisions of 21 CFR 1240.61, which regulation is the subject-matter of these proceedings.

6) At the request of Farmer Anonymous, commencing on March 30, 2010 I no longer represent him, but I have obtained the consent of Farmer Anonymous to present this Affidavit summarizing the course of communications, together with the correspondence which I pursued with the FDA while representing him concerning FDA's allegations of violation of 21 CFR 1240.61

7) On March 25, 2010 while speaking on the telephone with Melissa Mendoza, Esq., internal counsel to the FDA, and Steven Barber and Tina Pawlowski from the Detroit District office of the FDA, I confirmed with Mr. Barber that my previous correspondence with the FDA concerning Farmer Anonymous was in the possession of the FDA Detroit District Office as a part of the Administrative Record in his case; consequently, every document which is referred to in this Affidavit has been previously known to defendant FDA, and the identity of Farmer Anonymous is known to defendant FDA.

8) Farmer Anonymous was sent a Warning Letter by the FDA Detroit District Office in 2007 ("Warning Letter") because "Our investigation determined that your firm distributes unpasteurized raw milk and cream in interstate commerce in finished form for human consumption. Such distribution is a violation of the 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 letter goes on to describe the activities of Farmer Anonymous which is the basis for the allegation of violation: "The regulation prohibits the delivery into interstate commerce of milk and milk products in final package form for direct human consumption unless they have been pasteurized. The milk and cream you produce in [name of State redacted] and distribute to Cooperatives in [name of State redacted] and [name of State redacted] for further distribution to their Co-op members, is in final package form for direct human consumption." The letter demanded "action to correct this deviation and prevent any further recurrence. Failure to make prompt corrections could result in regulatory action without further notice." [Att A].

9) On February 21, 2007 FDA's headquarters office in Rockville, MD sent a letter to Senator Carl Levin (D-Mich) responding to his inquiries on my and others' behalf dated November 3, 2006, reiterating FDA's long-term and continuing position in support of 21 CFR 1240.61 and reiterating as well FDA's long-held position that 21 CFR 1240.61 applies to sales in interstate commerce. [Att B]

10) On February 27, 2007 I sent a letter to the Director of FDA's Detroit District Office confirming the opportunity for Farmer Anonymous and me to meet with the FDA to discuss the allegations contained in the Warning Letter. With my letter, which was copied to officials in FDA's headquarters offices, I enclosed a package of 232 testimonials (together with a summary thereof) concerning the benefits of raw milk and raw dairy products as perceived by a large group of consumers who obtained milk from Farmer Anonymous through a herd lease/cow share co-op arrangement. [Att C]

11) On March 6, 2007 Farmer Anonymous, his wife and I appeared in person at FDA's Detroit District Offices and met there at length with District Director Joann Givens, Compliance Branch Director David Kaszubski, Director of Investigations Keith Jasukaitis, and Compliance Officer Judith Jankowski. As well, FDA's Brandon Bergman from College Park and Dennis Downer from FDA's Indianapolis office, and FTCLDF's Peter Kennedy attended via conference telephone. In this meeting we requested that the FDA rescind the Warning Letter and discontinue enforcement, which request was denied.

12) FDA nevertheless agreed to a two-week extension to permit us to explain more fully the basis for our request that FDA withdraw the Warning Letter and discontinue its enforcement actions against Farmer Anonymous and the co-ops which utilized private herd lease/cow share arrangements.

13) By letter dated March 20, 2007 co-counsel Pete Kennedy of FTCLDF and I made detailed arguments to the FDA, in which we presented factual and legal analysis showing his activities to be outside FDA jurisdiction, and concluded with our request that FDA rescind the Warning Letter and discontinue enforcement against these private arrangements. [Att D]

14) On September 17, 2007 FDA responded to our March 20, 2007 request and stated that the request had been "forwarded to FDA's Center for Food Safety and Nutrition (CFSAN) for review." FDA and CFSAN flatly rejected our request, and closed by stating, "FDA does not support rescinding the Warning Letter or terminating any follow-up inspection and enforcement action." [Att E]

15) On September 26, 2007 I requested another meeting with FDA's Detroit District Office. [Att F]

16) On October 15, 2007 I cancelled the meeting request and proposed, alternatively, that Farmer Anonymous provide labeling of his milk containers compliant with 21 CFR 501.1, based on precedent with which I had become familiar concerning labeling by which we understood FDA to permit raw milk moving interstate if it was labeled as pet food. [Att G] This communication was not responded-to by FDA.

17) On March 20, 2008 I sent FDA a letter expressing concern that my October 15, 2007 letter had not been responded-to, particularly in view of then-emerging cases of FDA enforcement action, both civil and criminal, elsewhere in the country calling into question the pet food precedent upon which we had relied in the October 15 proposal. [Att H]. This communication was not responded-to by FDA.

18) On March 23, 2010 FDA appeared at the premises of Farmer Anonymous for an inspection pursuant to 21 USC 374(a). On March 25, 2010 I spoke with the FDA representatives as noted in paragraph 7 above, and in view of what appeared to be imminent enforcement action by FDA, Farmer Anonymous authorized me to propose an agreement to discontinue sending raw milk beyond state lines. [Att I]

19) The next day March 26, 2010, FDA's attorney Mendoza replied by asserting that Farmer Anonymous had "refused to allow FDA investigators to inspect." Responding to our Fifth Amendment concerns, Ms. Mendoza made it clear that their investigation was "to determine whether your client has violated and/or is violating [the laws].....If violations are found, FDA could initiate regulatory enforcement actions." In response to my inquiry whether Farmer Anonymous was the subject of a criminal investigation, she basically said she didn't think so, but couldn't really commit the agency one way or the other. In response to our offer to enter into an agreement to discontinue out of state raw milk shipments in return for some comfort concerning further enforcement actions, she said fine, but "FDA cannot, in the context of such a [settlement] decree or otherwise, make commitments regarding any additional legal action, on its own behalf or that of any other federal or state agencies." A two-hour deadline was given to me to respond, which I could not meet, and I asked for time over that weekend during which to contact my client and obtain his answer. [Att J, K]

20) On Monday, March 28, 2010, in view of what appeared to be certain enforcement consequences, I responded to Ms. Mendoza stating that I had been authorized by Farmer Anonymous to commit that he would terminate all supply of raw milk and raw milk products out ofstate.... [Att L]. (In this email I make reference to a press report, later found to have been in error, referring to "campylobacter positives." To date, no campylobacter positives have been identified in the milk supplied by Farmer Anonymous.) I asked Ms. Mendoza to call me to discuss the conduct of an inspection. This

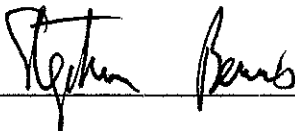
communication was not answered by FDA, and on the morning of March 29, 2010 the FDA inspected the premises of Farmer Anonymous.

21) On March 30, 2010 I advised Ms. Mendoza that Farmer Anonymous that morning had asked me to discontinue my representation of him.

22) Based on my dealings with FDA over the past three years, 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, even though no administrative, civil or criminal enforcement action has been taken by FDA against the farmer.

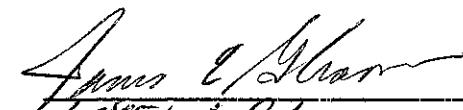
23) I certify that all of the documents attached hereto as Attachments A through L, inclusive, are copies of the originals and have not been materially altered in any way. I also certify that all of the attachments are in a file over which I have custody and that all of them were either sent to or sent by the FDA as a document that was generated in the ordinary course of business of either myself or of the FDA. I also certify that all of the attachments were generated at or about the time identified by the events depicted in each attachment.

FURTHER AFFIANT SAYETH NOT.



Stephen Bemis

Sworn and subscribed before me this 2 day of June, 2010.



JAMES E. GLEASON
Notary public
STATE of MICHIGAN
COUNTY OF LIVINGSTON
ACTING AT LIVINGSTON

My Commission Expires: 6/5/15

ATTACHMENT A

ATT A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2007 DT-06

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313 393-8100
FAX: 313 393 8109

February 8, 2007

[REDACTED] Owner

[REDACTED]

[REDACTED]

[REDACTED]

Dear [REDACTED]

A joint investigation by the U.S. Food and Drug Administration, the Indiana Board of Animal Health, and the Michigan Department of Agriculture, has documented violations of the Public Health Service Act (PHS Act) and a Federal regulation promulgated under the PHS Act.

Our investigation determined that your firm distributes unpasteurized raw milk and cream in interstate commerce, in finished form for human consumption. Such distribution is a violation of the 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 prohibits the delivery into interstate commerce of milk and milk products in final package form for direct human consumption unless they have been pasteurized. The milk and cream you produce in Indiana and distribute to Cooperatives in Michigan and Illinois for further distribution to their Co-op members, 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 29,509 (Aug 10, 1987).

The above observation is not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the PHS Act and implementing regulations. You should take prompt action to correct this deviation and prevent any future recurrence. Failure to make prompt corrections could result in regulatory action without further notice.

In addition to the violation above, we have several comments concerning the lack of labeling of your raw milk and cream products. First, we note that your raw milk and cream products do not contain labeling that specifies the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5). We also note that your raw milk and cream products do not contain a principal display panel bearing a declaration of the net quantity of contents (21 CFR 101.105). Lastly, we note that your raw milk and cream products fail to have labels that declare their ingredients (21 CFR 101.4).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

ATT "A"

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Page 2
W/L DT-86

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 can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be directed to Judith A. Jankowski, Compliance Officer, at the above letterhead address. If you have any questions regarding any issues in this letter, please contact Ms. Jankowski at 313-393-8125.

Sincerely,



Joann M. Owens
District Director
Detroit District Office

[REDACTED]

[REDACTED]

[REDACTED]

ATTACHMENT B

ATT "B"
LEVIN 01002

02 24 07 WED 12 06 FAX 301 443 2567

DHHS FDA 01



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

The Honorable Carl Levin
United States Senator
177 Michigan Avenue
Room 1860
Detroit, MI 48226

FEB 21 2007

Dear Senator Levin:

Thank you for the letter of November 3, 2006, on behalf of your constituents, members of the [REDACTED] who expressed concern about the U.S. Food and Drug Administration's (FDA or the Agency) activities in enforcing regulations governing the interstate sale of raw milk and about FDA's regulatory policy related to cow-share agreements. We apologize for our delay in responding.

FDA, the Centers for Disease Control and Prevention, state public health agencies, as well as the American Medical Association and American Academy of Pediatrics, consider raw milk a public health safety hazard. In addition, FDA considers the cow-sharing agreements it has observed to be an attempt at circumvention of section 1240.61 of the Agency's regulations (Title 21 of the *Code of Federal Regulations* [CFR] § 1240.61). That section prohibits the sale and distribution in interstate commerce of milk in final package form for direct human consumption unless it has been pasteurized.

Below are responses to the three questions in your request:

1. Why is the FDA investigating the [REDACTED]? Will there be any enforcement action as a result? If so, please provide information regarding the timeline, procedures, and appeal rights under this process.

FDA was alerted by the Michigan Department of Agriculture to interstate shipments of raw milk into Michigan from [REDACTED] farm, located in Indiana. Concurrently, the Indiana Board of Animal Health was also advised of the situation.

Because of the significant public health concerns associated with raw milk, FDA determined that an investigation of [REDACTED] should be conducted to ensure that the general public, including people living in Michigan and Indiana, are protected from the dangers of raw milk.

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02/21/07 WED 12:06 FAX 301 443 2567

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Page 2 – The Honorable Carl Levin

Following a request from the Michigan Department of Agriculture, FDA with the Indiana Board of Animal Health and the Michigan Department of Agriculture jointly investigated [REDACTED] farm, [REDACTED] to determine the circumstances related to the production, sale, and distribution of raw milk and raw milk products in Michigan, Indiana and Illinois.

One of the results of the investigation was that a warning letter dated February 8, 2007 was delivered to [REDACTED] for violations of the Public Health Service Act (PHS Act), Title 42 of the *United States Code* (U.S.C.) § 271 (a), and 21 CFR § 1240.61 which were documented during the FDA/State inspection.

The warning letter requests that [REDACTED] notify FDA in writing, within 15 working days, of the specific steps he has taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

2. Has the FDA previously investigated interstate cow-sharing agreements?

If so, please provide examples of the investigations as well as the FDA's determination in those cases.

Yes. FDA has investigated cases where cow-sharing agreements were involved. For example, in December 2005, FDA investigated Dee Creek Farms, in Woodland, Washington, when an outbreak of 18 cases of *E. coli* O157:H7 infection, including two children with Hemolytic Uremic Syndrome (HUS), was linked to raw milk in Washington and Oregon. HUS occurs after an *E. coli* O157:H7 infection of the digestive system and is the most common cause of sudden, short-term kidney failure in children. FDA determined that Dee Creek Farms caused to be delivered into interstate commerce unpasteurized milk in finished form for human consumption in violation of the PHS Act, 42 U.S.C. § 271 (a) and 21 CFR § 1240.61 and issued a warning letter to Dee Creek Farms dated May 2, 2006. FDA was aware that cow-sharing was a method of Dee Creek Farms' distribution.

Another investigation involved Double O Farms in Verona, Kentucky. On June 7, 2006, FDA issued a warning letter to Double O Farms because the firm was found to be distributing unpasteurized milk in interstate commerce. The firm sent a written response to FDA stating they would cease interstate shipment of unpasteurized milk.

3. Are there provisions under FDA regulations that allow citizens to purchase and consume raw milk? If so, what are the circumstances under which citizens can or cannot do this?

FDA strongly advises against the consumption of raw milk and prohibits the sale of unpasteurized milk and milk products in interstate commerce. States regulate the intrastate sale of raw milk. Indiana and Michigan prohibit the sale of raw milk for human consumption.

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02/21/07 WED 12:07 FAX 301 443 2587

DHHS FDA OL

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Page 3 - The Honorable Carl Levin

Thank you again for contacting us concerning this matter. If you have any further questions, please let us know.

Sincerely,



Michele Mital
Acting Deputy Assistant Commissioner
for Legislation

ATTACHMENT C

ATT "C"

STEPHEN T. BEMIS
ATTORNEY AT LAW
6500 Jennings Road
Ann Arbor, Michigan 48105
(734) 994-8496

February 27, 2007

Joann Givens
Detroit District Director
FDA, Detroit District Office
300 River Place
Suite 5900
Detroit, Michigan 48207

Re: [REDACTED]

Dear Ms. Givens:

I understand from Pete Kennedy that I may be able to meet with you in the near future concerning [REDACTED] situation with [REDACTED]

Prior to that meeting I am taking the liberty of forwarding to you a package of testimonials that you may find helpful in understanding some of the background.

Please be advised, that certain individuals' testimonials may utilize informally the terms "buy" and "sell". These and similar terms do not properly describe the underlying legal relationship based on formal herd-lease agreements and each members' cow-share agreement. In every case (other than informal sharing of pick-up duties among neighbors who are members), only co-op members may obtain raw milk pursuant to their individually-signed cow-share agreements, and in any case, we are able to provide duly executed copies of such agreements.

I look forward to meeting with you and your staff and in discussing this and other aspects of this matter.

Very truly yours,

Stephen T. Bemis
(cell 734-646-6091)

STB/dr
Enclosures

cc Michelle Mital - FDA (DC)
Captain Robert Hennes - FDA (College Park)

ATTACHMENT D

ATT "D"

STEPHEN T. BEMIS
Attorney at Law
21001 Van Born Road
Taylor, Michigan 48180
313-792-6360

March 20, 2007

VIA E-MAIL AND EXPRESS MAIL

Ms. Judith A. Jankowski
Compliance Officer
Department of Health and Human Services
U.S. Food and Drug Administration
300 River Place
Suite 5900
Detroit, Michigan 48207

RE: Warning Letter 2007-DT-06
[REDACTED]

Dear Ms. Jankowski:

This letter is our promised written response, following our meeting on March 6, 2007, to the foregoing Warning Letter dated February 8, 2007, received by [REDACTED] on February 12, 2007. We responded verbally to the Warning Letter at our meeting in your offices, at which time a two week extension was granted within which to submit this expanded written response. As we discuss herein at length, we believe the Warning Letter must be rescinded and further enforcement action against [REDACTED] and the co-ops must be terminated.

FACTUAL BACKGROUND

As you know, this case involves three herd-lease agreements entered into by [REDACTED] and his [REDACTED] farm [REDACTED] (collectively, [REDACTED] with three cooperatives located out of state ([REDACTED] in Michigan, [REDACTED] in Illinois and [REDACTED] in Michigan). Each of these cooperatives in turn, is comprised of a manager and individual members who participate in their co-op's herd lease via individually-executed member cow share agreements, to obtain raw milk and other foods, and pursuant to which each member agrees to pay an annual cow share lease fee which is applied to the annual herd lease agreement and to other operational expenses of the co-op.

The herd leases entered into between [REDACTED] and the co-ops stipulate a boarding fee expressed as the sum of \$2.00 per 1/2 gallon of milk (\$4.00 per gallon, subsequently increased by \$.25 per gallon) which each of the three co-ops has agreed to pay to [REDACTED] for its boarding services for the

ATT "A"

Ms. Judith A. Jankowski
 March 20, 2007
 Page 2

herd during each year's lease. The parties determined the boarding fee to be a convenient method to allocate production costs of feeding and caring for the herd, as well as to cover all labor and equipment required in milking them and storing the products prior to weekly pickups and deliveries by the co-op managers or their designees. Each of these four entities (██████████ and the three co-op managers) is small, family-owned and family-staffed. In each case, the co-ops charge additional fees to members to obtain and deliver the milk to the various drop-off locations, where members take delivery of their milk and remit a combined fee per gallon for the services rendered by each of ██████████ and the co-op manager.

ECONOMIC MODEL FOR THE AGREEMENTS

Each of these herd-lease and corresponding co-op member cow share agreements is valid, commercially grounded, and legal under applicable state and federal law. Specifically, each herd lease's annual fee is based on the estimated slaughter value for such a cow, divided by her estimated nine year useful life as a milker, multiplied by the number of cows under the lease. In other words, the economic model utilized, is that each year, a co-op pays the pre-agreed lease fee to obtain dairy products derived from one-ninth of each cow's useful production life. Hence, in the case of ██████████, the approximate slaughter value of \$300 for a Jersey cow past her milking years is divided by 9, yielding an annual economic lease value of \$33.33, multiplied by 41 head to yield \$1376. This is the derivation of the annual lease fee of \$1383 for a herd of 41-46 head as recited in the ██████████ contract.

COW SHARES AND THE LAW

FDA's Interpretations of 21CFR 1240.61 Apply It Only to Sales

It took a public-interest lawsuit culminating in 1987 (*Public Citizen vs. Heckler*, 653 F. Supp. 1229) [Ex A] to order the FDA to publish a proposed rule "banning the interstate sale of all raw milk and raw milk products." (at page 1242) after the Agency, presumably for good and certain reasons, had delayed taking action for fully 14 years prior. As discussed below, this court order caused the Agency to propose a rule which (for reasons we have not been able to determine from the regulatory record) became transformed into much broader language which was issued under the communicable disease provisions of 42 USC 264(a) and the contaminated food provisions of the Food, Drug and Cosmetic Act at 21 USC 342(a) (1), (3), and 4 and 371(a), which we shall discuss in more detail below.

Although the Agency cites the broad language of 21 CFR 1240.61 in its Warning Letter, in fact FDA has up until this case, utilized its regulation only rarely to issue Warning Letters in cases other than sales and more significantly, in its own publications and other writings FDA has characterized the rule as applying only to sales. For example, in a press release issued on March 1, 2007 [Ex B], the Agency cited several of its own previous publications, including the following paragraph from its publication entitled "Got Milk? Make Sure It's Pasteurized" (September-October 2004 Issue) where the words "sale", "sold" and "sell" and *no others* are used repeatedly to characterize both 21 CFR 1240.61 and applicable state laws:

ATT "D"

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March 20, 2007
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The Law

It is a violation of federal law enforced by the FDA to sell raw milk packaged for consumer use across state lines (interstate commerce). But each state regulates the sale of raw milk within the state (intrastate), and some states allow it to be sold. This means that in some states dairy operations may sell it to local retail food stores, or to consumers directly from the farm or at agricultural fairs or other community events, depending on the state law.

In states that prohibit intrastate sales of raw milk, some people have tried to circumvent the law by "cow sharing," or "cow leasing." They pay a fee to a farmer to lease or purchase part of a cow in exchange for raw milk, claiming that they are not actually buying the milk since they are part-owners of the cow. Wisconsin banned cow-leasing programs after 75 people became infected with *Campylobacter jejuni* bacteria in 2001 from drinking unpasteurized milk obtained through such a program. [Ex C]

Further, as recently as last month, in its February 21, 2007 written reply to Senator Carl Levin (D-Michigan), the FDA stated, "That section [referring to 21 CFR 1240.61] prohibits the sale and distribution in interstate commerce of milk in final package form for direct human consumption unless it has been pasteurized." The conjunctive construction "sale *and* distribution," is obviously a much narrower construction than the regulation, and the Agency concludes its letter to the Senator, "FDA... prohibits the sale of unpasteurized milk and milk products in interstate commerce." And again (just as they did in the referenced 2004 broadside quoted above), the Agency ventures to characterize to Senator Levin the state laws: "Indiana and Michigan prohibit the sale of raw milk for human consumption." [Ex D]

Senator Levin had written the FDA on November 3, 2006 specifically inquiring about the Agency's position in its investigation of [REDACTED] and the related Michigan investigation of [REDACTED] [Ex E] More than three months later, after the Detroit office issued its Warning Letter to [REDACTED], the FDA's Rockville office issued what one would suspect would be a carefully prepared answer to the Senator's questions. There certainly was ample time for review and correct phrasing for the Agency to establish, and indeed confirm its several-years' position that 21 CFR 1240.61 applies only to sales.

State Law and Administration Apply to Sales Only

Michigan

Michigan's laws contemplate arrangements for the boarding (leasing) of cattle (MCL 570.185) as in the herd-lease and cow shares in this case, and applicable UCC provisions as adopted by Michigan make clear the distinction between "sale" and "lease" (MCL 440.2106 defines "sale"; MCL 440.2102 defines the statute's applicability to "sales" of "goods"; MCL 440.2803(h) defines "goods," and (j) defines "lease"; and finally, MCL 440.2802 specifies the statute's applicability to leases). The definition of lease describes the herd leases here: "a transfer of the right to possession and use of goods for a term in return for consideration..." And finally, in the

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 Page 4

cited (j) definition of "lease," the law makes it clear that "a sale... is not a lease." [collectively, Ex F]

Since under the [REDACTED] herd leases and corresponding cow share agreements the goods in question (raw milk) are subject to leases, there are no sales, and consequently, the otherwise-relevant provisions of the Grade A Milk Law of 2001 (MCL 288.538 and 288.696) are not applicable since they are limited to sales: "Only pasteurized milk and dairy products shall be offered for sale or sold, directly or indirectly, to the final consumer..." Finally, the definition in MCL 288.475(f) of offering for sale makes it clear, again, that leases are not included as sales [Ex G]. Indeed, in a telephone conversation on February 1, 2007 the writer was advised by Katherine Fedder, the Director of the Food and Dairy Division of the Michigan Department of Agriculture that MDA had obtained an "informal" opinion substantially to the foregoing effect from the Michigan Attorney General's office, pursuant to which the Division discontinued issuing warning letters to cow share operations within Michigan sometime in the 2003-2004 time frame. Finally, since Michigan statutes contemplate only sales (and not herd lease/cow shares as in this case), under common law the leasing arrangements are fully legal. Indeed, in a 1937 Supreme Court case which is still good law in Michigan, a farmer distributing surplus raw milk to neighbors was held not to be delivering milk to the public in violation of then-applicable statute, and the case's definition of the public vs. private parties, central to the case's finding, is still instructive in interpreting the essentially private nature of the lease agreements in the present situation (*People v. Powell*, 280 Mich. 699 (1937), 273 N.W. 371). [Ex H]

Indiana

Indiana has also adopted the UCC, relevant portions of which also make the distinction, as in Michigan, between lease and sale:

(j) "Lease" means a transfer of the right to possession and use of goods for a term in return for consideration, but a sale, including a sale on approval or a sale or return, or retention or creation of a security interest is not a lease. Unless the context clearly indicates otherwise, the term includes a sublease. (IC 26-1-2.1-103(1)(j)) [Ex I]

While sales of raw milk are prohibited in Indiana, in the case of [REDACTED] lease agreement the actions (or lack thereof) of the Indiana Board of Animal Health appear to indicate that the Agency does not view [REDACTED] operations as involving sales of raw milk. In fact, despite [REDACTED] previous well-known reputation as a top quality Grade A licensee subject to Indiana jurisdiction, when in June, 2004 [REDACTED] began to discontinue his Grade A operation and began switching over to raw milk supply under the herd leases, Indiana regulators made no attempt to warn him or advise him against such activity.

We are prepared to demonstrate specific and continuing knowledge by Indiana and FDA regulators of the raw milk operations conducted by [REDACTED] for a period in excess of 2-1/2 years, during which time [REDACTED] was permitted to build an investment, and a business model, devoted to and dependent upon these herd lease agreements supplying raw milk. Specifically, in June, 2004 [REDACTED] freely gave his Indiana regulatory contact a copy of his raw milk herd lease

ATT "D"

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agreement, and that regulator told [REDACTED] in turn that he had provided a copy of the agreement to the FDA interstate tank truck inspector.

Considerations in Federal Laws Underlying the Regulation

Food Drug and Cosmetic Act (21 USC 321(b))

Even if, contrary to the above-cited provisions of Federal/FDA interpretive guidance and administrative practice in [REDACTED] specific case, and even if, contrary to Michigan and Indiana law and administrative practices, [REDACTED] lease arrangement were construed to be a sale, it would still fall outside of FDA's jurisdiction under the regulation (21 CFR 1240.61).

Notwithstanding, that the Federal Food, Drug and Cosmetic Act defines "interstate commerce" in 21 USC 321b, the word "commerce" itself is not defined in the Act. In the absence of such a definition, which is central to the distinction here in question (e.g., is there here a lease or a sale, and are either or both subsumed in "commerce?"), state law would apply under *Erie Railroad v. Tompkins*. In 2006 an Indiana Appellate Court adopted the definition of "commerce" contained in *Black's Law Dictionary*: "the exchange of goods, productions, or property of any kind; the buying, selling, and exchanging of articles." [*Rice v. Allen County Plan Com'n*, 852 N.E.2d 591] [Ex J] [REDACTED] lease arrangement would fall outside this definition. There is no sale or exchange of the milk here because the co-op members already have title to the milk by virtue of their herd-lease cow share agreement with [REDACTED] through the co-ops.

Furthermore, if [REDACTED] lease were ultimately found to be interstate commerce, then enforcing 21 CFR 1240.61 against [REDACTED] would be a violation of his Fifth Amendment substantive due process rights. In *Village of Euclid v. Ambler Realty Co.*, 272 U.S. 365 (1926), the Supreme Court held that a law was a violation of substantive due process if it was "clearly arbitrary and unreasonable, having no substantial relation to the public health, safety, morals or general welfare." [Id. p. 395] *Euclid* was recently cited for its due process precedent by the Court in *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 529 (2005). [Ex K]

Enforcement action against [REDACTED] would be arbitrary because of the dairy's exemplary track record for producing clean, sanitary milk. Indeed, this record of quality was a central determining factor in [REDACTED] selection of [REDACTED] when [REDACTED] interviewed dairies in 2004 preparatory to identifying a raw milk supplier with whom to enter into a lease. When [REDACTED] was a licensed Grade A dairy, its *raw milk* standard plate counts consistently tested *below* the Pasteurized Milk Ordinance ("PMO") limit for milk that had been *pasteurized* (20,000 SPC). The PMO is the model governing document for interstate shipments of milk for human consumption.

The "Headrick Paper on the Epidemiology of Raw Milk-Associated Foodborne Illness Outbreaks" reported that 38 out of the 46 raw milk-associated foodborne illness outbreaks found from 1973 to 1992, the implicated milk was produced at a commercial dairy. [Ex L] While a Grade A licensee, [REDACTED] was not a commercial dairy. Given the overwhelming evidence in the Headrick study (e.g., 83% of raw milk outbreaks, which in total averaged only slightly more than two per year, were in commercial dairies not in small family operated farms), there is no

ATT "D"

Ms. Judith A. Jankowski
 March 20, 2007
 Page 6

compelling reason now to focus on [REDACTED], or any other operation which by its track record shows itself to be a model of healthy cleanliness.¹ In other words, the administrative decisions by both the Indiana and FDA officials in permitting [REDACTED] raw milk operations to move forward, were vindicated both prospectively in practice and retrospectively under the epidemiological study of these previous periods. Hence, the FDA's newly commenced "one-size fits all" approach to raw milk enforcement arbitrarily discriminates against a clean farm like [REDACTED].

Further, enforcement action against [REDACTED] has "no substantial relation to the public health, safety, morals or general welfare." Such an enforcement action is not protecting the public health; rather, it is interfering with the liberty of the co-ops' members to do what they believe best for the health of themselves and their families

Specifically, there is no conclusive evidence that any of the very few foodborne illnesses associated with the consumption of raw milk has been secondarily transmitted to someone who did not consume the raw milk linked to the illness. Mead's definitive paper on foodborne illnesses does not even mention the possibility of secondary transmission. [Ex M] *Morbidity Mortality Weekly Report* mentions only one case in which CDC hypothesized there was a secondary transmission of foodborne illness caused by the initial consumption of raw milk. In that case CDC provided no proof to support their claim.² [Ex N] In tables published for several years in the mid-1990's, CDC reported single-digit numbers of outbreaks and small numbers of total cases attributable to milk (including raw milk), consistently reporting milk's portion of food-borne diseases as less than 1% (and usually less than 0.5%) for both number of outbreaks and numbers of cases, with no deaths, for the years 1993, 1994, 1995, 1996 and 1997. [Ex O]

Again, in the absence of any compelling epidemiological facts, the consumption of raw milk supplied from ethical and clean operations such as [REDACTED] has not demonstrated any signs of incipient danger to the public health. Locally produced raw milk, supplied by farmers known to the consumer, have an inherent safety mechanism: if there's a problem with the milk, the farmer's phone rings. The testimonials gathered from 232 co-op members (discussed at more length below) include literally no mention of any sickness or other quality problem with any of [REDACTED] raw milk or other dairy products.

Communicable Disease (42 USC 264)

The other principal statutory foundation for 21 CFR 1240.61 was 42 USC 264, the statute regulating communicable diseases, effectively classifying raw milk with obviously dangerous and notorious communicable diseases such as cholera, smallpox, and the ebola virus (among others, as specified in Executive Order 12452, contained in 42 USC 264). We submit, it was an overreach to promulgate this regulation on the basis of the government's power to regulate such communicable diseases. [Ex. P]

¹ In passing, the Headrick Paper begs the question of whether this and similar studies of the danger of raw milk cited by FDA in its various communications, are based on raw milk obtained from cows in confinement dairy operations which are not managed to eliminate the need for pasteurization

² Again, the CDC report does not make clear, whether or not the raw milk in these cases was obtained from cows managed to preclude the need for pasteurization

ATT "D"

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Page 7

The regulation banning raw milk in interstate commerce is found in part 1240 of Title 21 CFR (Control of Communicable Diseases), subpart D (Specific Administrative Decisions Regarding Interstate Shipments). In addition to the ban on raw milk, the other regulations under subpart D are titled as follows:

- 1240.60 Molluscan shellfish (regulation does not ban interstate shipment)
- 1240.62 Turtles intrastate and interstate requirements
- 1240.63 African rodents and other animals that may carry the monkey pox virus
- 1240.65 Psittacine birds
- 1240.75 Garbage.

In light of the above regulations, it seems out of place to ban a food that has benefited the health of so many and that was the cause (83% in commercial dairies) of only slightly more than two outbreaks per year of foodborne illnesses from 1973 to 1992. Likewise, it seems out of place to issue a regulation banning raw milk interstate under the authority granted by 42 USC 264 in light of the communicable diseases listed in that statute. For example, in a case involving the interstate sale of turtles decided in 1977, the court cited the pervasive and persistent infection (over 50% reinfection rate) of turtles with *salmonella* as persuasive of the need to regulate the creatures in interstate commerce. [Ex Q] Raw milk offers no such compelling risk, and the epidemiology and ██████████ track record both attest to this.

Again, although for the above reasons we would urge the FDA to re-examine the foundations of 21 CFR 1240.61, we nevertheless contend, particularly in light of the inconsistent interpretation and enforcement positions taken by FDA and state regulators, specifically against ██████████, that continued enforcement in this matter would clearly be violative of ██████████ constitutionally protected rights to due process and liberty and property under the Fifth Amendment, as well as violative of the co-op members' right to liberty and property under the Fifth Amendment.

THE SCIENCE AND THE OPINIONS

In addition to the foregoing CDC and other data, we are compelled to address the FDA's regular assertions that raw milk is dangerous and has no proven nutritional offsetting benefits. It is axiomatic that no member of ██████████ or the other coops would knowingly drink unpasteurized milk from a conventional dairy which is not managed to eliminate the need for pasteurization. As noted above, ██████████ operations and milk are exemplary in their cleanliness.

Individuals' reports of the benefits of raw milk are apparently scoffed-at by the FDA, as recently as in its March 1, 2007 release where it stated flatly: "Research has shown that these claims are myths." [Ex B] Well, at least raw milk advocates weren't called ignorant peasants! We would certainly like to read some of this unspecified research. Most of the attachments to the March 1 release on the topic of (lack of) raw milk benefits were repetitive internal Agency assertions

ATT "D"

Ms. Judith A. Jankowski
 March 20, 2007
 Page 8

We have previously furnished you with 232 testimonials concerning the benefits which individuals perceive in consuming raw milk. [Not supplied again due to their volume; Tally Sheet Ex. R] Many of these cite persuasive individual cases of nutrition-based medical problems which were reversed or ameliorated due to consumption of raw milk. A number of these testimonials were written by doctors and other health professionals, not to mention professionals in other fields who are not wont to throw words around carelessly. Nearly 50% of the total 232 reported an improvement in their health in general terms, and 45 (nearly 20%) reported quite specific experiences in being able to consume raw milk after (for years in many cases) being unable to drink pasteurized milk. At some level, "anecdotal" evidence transforms by its weight and focus into something more persuasive. Certainly the individuals who care passionately about their health, or the health of children (50% mentioned concern for children or grandchildren), believe raw milk is vitally important for future generations: (you heard our client express this exact sentiment when we met on March 6). Finally, the single largest concern expressed by respondents (63%) was to be able freely to choose the foods they wished to eat. These feelings run deep and strong, and the Agency needs to listen to them.

Finally, contrary to the Agency's assertions, there are studies which demonstrate the benefits of raw milk. We refer you to the abstract of a recent study published in the *Journal of Allergy and Clinical Immunology* where 4700 children were studied and it was concluded that raw milk provided a 40% reduction in incidences of eczema and a 10% reduction in hay fever. [Id, Vol 117, Issue 6, Pages 1374-1381 (June, 2006) [Ex S] and, although not a study of raw milk, there were dramatic results recently reported in the journal *Human Reproduction* where the authors concluded, "high intake of low-fat dairy foods may increase the risk of anovulatory infertility whereas intake of high-fat dairy foods may decrease this risk." [Id, "A Prospective Study of Dairy Foods Intake and Anovulatory Infertility", pages 1-8 (2007) [Ex T]. Given the media attention to a subject of such emotion and urgency (starting with a New York Times "Health" section article) [Ex U], it won't take a leap of logic for women suffering infertility, who are also intolerant of pasteurized milk (nearly 20% of the population in our testimonials), to consider strongly trying a little raw milk. We suggest an infertility study utilizing raw milk would produce even more dramatic results.

If FDA is truly interested in the public health, it should take the opportunity to design and implement research to explore the hypothesis, suggested in the testimonials and in such emerging studies, that nutritional interventions such as raw milk can provide cure (rather than just symptomatic relief) for illnesses such as eczema, asthma and hay fever (and perhaps others) as well as solve the riddle of widespread intolerance to pasteurized milk, which the Congress has recognized with the passage of legislation such as the Food Allergen Labeling and Consumer Protection Act (Public Law 108-202 of 2004)

CONCLUSION

For the reasons advanced above, the Agency should withdraw its Warning Letter and refrain from further enforcement against [REDACTED] and [REDACTED] and the three co-ops contracting with [REDACTED]. The herd lease/cow share contracts are not circumventions of law, but rather are in compliance with applicable law, entered into by persons knowledgeable concerning

ATT "D"

Ms Judith A Jankowski
March 20, 2007
Page 9

the demonstrably small risks which they choose to assume in exchange for substantial perceived benefits. We understand the Agency's concern with the potential for widespread abandonment of pasteurization standards for the public at large. This concern need not extend to the small realm of private contractual cow share/herd lease arrangements among consenting adults. We submit that the FDA has many greater priorities in its long list of regulatory responsibilities, than attempting to enforce rules which are both unnecessary and arguably counterproductive to some real possibilities for improved health.

The FDA's inconsistent administrative history (e.g., its historic and current description of its mandate as applying to sales, as opposed to the case at hand) concerning enforcement against cow share arrangements, and indeed its historic reticence to devote resources to this area, should not now be turned against [REDACTED] on the basis of administrative whim or preference or worse. This is not to mention the legal questions discussed above both in state law and under the enabling federal statutes. Further action against our client would be the essence of discriminatory, harassing law enforcement and must not occur.

We appreciate this opportunity to share our response to FDA's concerns in this matter, and we trust that we may expect the Agency's commitment, as requested above, to withdraw its Warning Letter and to discontinue further scrutiny of [REDACTED] operations and its herd lease/cow share arrangements. Would you please send any response directly to [REDACTED] via U.S. mail and send copies to the undersigned.

Thank you.

Very truly yours,

Stephen T. Bemis, Esq.
Michigan Bar P-31599

Peter D. Kennedy, Esq.
9117A Midnight Pass Road
Sarasota, Florida 34242
Tel: 941-349-4984
Fax: 941-312-0654
e-mail: gifestmnrns@earthlink.net

SIB/dr

Enclosures

cc: Honorable Carl Levin, United States Senate

ATTACHMENT E

ATT "E"



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 3900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-6139

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 17, 2007

██████████ Owner
██████████
██████████
██████████

Dear ██████████

This letter is in response to the March 20, 2007 letter submitted to FDA by your attorney, Stephen T. Bemis (copy attached). In the letter Mr. Bemis requested that FDA review the response to Warning Letter 2007-DT-06 submitted on your behalf. Mr. Bemis requested FDA rescind the Warning Letter and terminate further enforcement action against you, ██████████ and the co-ops who receive your raw unpasteurized milk products. The letter did not address the misbranding charge cited in the Warning Letter. The letter and package of documents provided by Mr. Bemis were forwarded to FDA's Center for Food Safety and Nutrition (CFSAN) for review.

CFSAN has reviewed the material submitted by Mr. Bemis on behalf of ██████████ and found the written response to be inadequate. The response fails to include the specific steps that your firm will take or has taken to correct the violations. It is noted that your response refutes FDA's position that "herd leasing" to customers in neighboring states can be considered "interstate commerce." FDA does not agree with this position. In addition, FDA does not support rescinding the Warning Letter or terminating any follow-up inspections and enforcement action.

Any response to this letter should be directed to Judith A. Jankowski, Compliance Officer, at the above letterhead address. If you have any questions regarding any issues in this letter, please contact Ms. Jankowski at 313-393-8125.

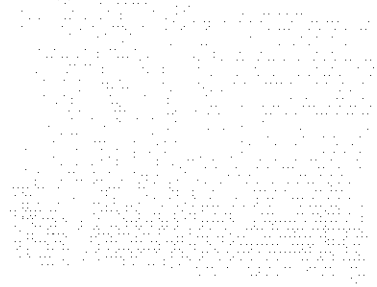
Sincerely,

Judith A. Jankowski
Compliance Officer

Attachment: a/s

cc: Stephen T. Bemis, Esquire
21001 Van Born Road
Taylor, Michigan 48180

Peter D. Kennedy, Esquire
9117A Midnight Pass Road
Sarasota, Florida 34242



ATTACHMENT F

ATT "F"

STEPHEN T. BEMIS
Attorney at Law
21001 Van Born Road
Taylor Michigan 48180
313-792 6360

September 26, 2007

Ms. Judith A. Jankowski
Compliance Officer
Department of Health and Human Services
U.S. Food and Drug Administration
300 River Place
Suite 5900
Detroit, Michigan 48207

RE: Warning Letter 2007-DI-06
[REDACTED]

Dear Ms. Jankowski:

We are in receipt of your letter dated September 17, 2007 concerning [REDACTED] situation.

I would like to speak with you concerning this, but understand that you will not return to the office until October 15, 2007. Your colleague (to whom you referred calls in your absence) said I should address myself to you when you return.

Consequently, upon your return, I will give you a call, and will plan as well, to provide you additional response concerning this matter.

Please contact me with any questions. Thank you.

Very truly yours,

Steve Bemis

SIB/dr

cc: [REDACTED]

Peter Kennedy, Esq.

ATTACHMENT G

ATT "6"

STEPHEN T. BEMIS

Attorney at Law
21001 Van Born Road
Taylor, Michigan 48180
313-792-6360

October 15 2007

Ms Judith A. Jankowski
Compliance Officer
Department of Health and Human Services
U.S. Food and Drug Administration
300 River Place
Suite 5900
Detroit, Michigan 48207

Re: Warning Letter 2007-DT-06
[REDACTED]

Dear Ms. Jankowski:

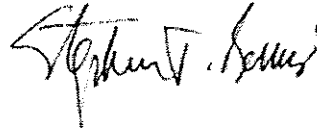
This letter is in further response to yours of September 17, 2006⁸ addressed to
[REDACTED]

Our client has decided to forego additional discussion with the Agency concerning the merits of the various arguments expressed in our recent exchange of correspondence.

We propose labeling compliant with 21 CFR 501.1 et seq., a draft sample of which is enclosed. This label would be imprinted on the gallon jug's cap closure.

Thank you for your kind assistance in this matter.

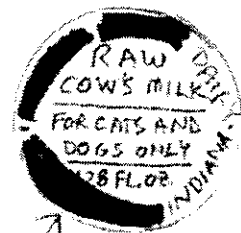
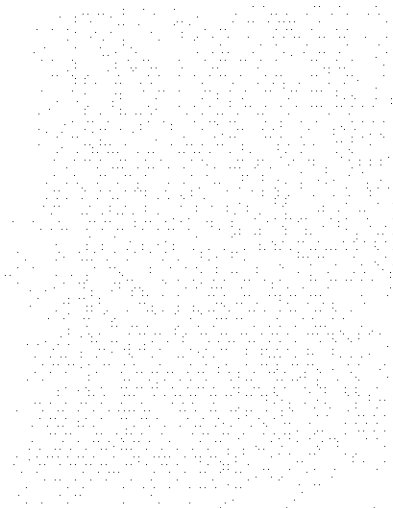
Very truly yours,



SIB/dr
Enclosure
cc. [REDACTED]

Peter Kennedy, Esq.

ATT



↑
WOULD NOT BE SMALLER
THAN 1/16" HIGH.

ATTACHMENT H

ATT "H"

STEPHEN T. BEMIS
Attorney at Law
21001 Van Born Road
Taylor, Michigan 48180
313-792-6360

March 20, 2008

VIA CERTIFIED MAIL

Ms Judith A Jankowski
Compliance Officer
Department of Health and Human Services
U S Food and Drug Administration
300 River Place
Suite 5900
Detroit Michigan 48207

313-393-8125
out of office until 4/22
SAB 3/16/08

Re: Warning Letter 2007-DI-06
[REDACTED]

Dear Ms Jankowski

Confirming the detailed message left in your voice mail today, I am writing to follow up on my most recent correspondence to you dated October 15, 2007 (copy attached)

At that time I proposed a form of labeling for [REDACTED] raw milk shipments which would bring him into compliance with 21 CFR 501.1 et seq. This proposal was made in good faith response to the repeated references made in both of FDA's letters to him on the topic, both of which made explicit reference to perceived labeling deficiencies.

Since my last communication, we have heard nothing further from your office. I am now apprised of other actions apparently being taken by FDA in other parts of the country, concerning similar interstate situations, with possible enforcement intent.

Consequently, we wish to obtain explicit clarification from FDA concerning the appropriateness of the continued use of the labels as proposed in my last correspondence.

Thank you very much

Very truly yours,

Stephen T. Bemis

STB:dr
Enclosure
cc. [REDACTED]
Peter Kennedy, Esq

ATTACHMENT I

ATT "I"

From: Steve Bemis <stbemis@charter.net>
Subject: **ASSERTION OF FIFTH AMENDMENT RIGHTS AND SETTLEMENT PROPOSAL**
Date: March 25, 2010 12:19:22 PM EDT
To: melissa.mendoza@fda.hhs.gov, steven.barber@fda.hhs.gov, tina.pawlowski@fda.hhs.gov
Bcc: FTCLDF President Pete Kennedy - <pete@ftcldf.org>, "David Cox G" <dcoxlaw@columbus.rr.com>

Dear Ms. Mendoza, Mr. Barber and Ms. Pawlowski - Thank you for the opportunity to discuss FDA's request for an inspection of the [REDACTED] facility, [REDACTED] owner ([REDACTED]) at [REDACTED]

Confirming our conversation earlier this morning, you had indicated the FDA was following up on its two visits to [REDACTED] this past Tuesday, and FDA has so far, determined that it was not a "refusal" for [REDACTED] to assert his Fifth Amendment right with respect to the inspection. In our second conversation concluded in recent minutes, Ms. Mendoza advised me that she is aware of no ongoing criminal investigation, that [REDACTED] and [REDACTED] are not a target, but that she would check further in the Agency concerning my question as to whether FDA is going further than the civil compliance side which you folks are administering.

As we discussed, in the circumstances (and in view of some three years of non-response from FDA concerning the [REDACTED] situation), my client has a high level of concern if he were to waive his Fifth Amendment rights and permit the inspection. As you know, it is our position that the herd lease/cow share arrangements under which [REDACTED] operates are outside FDA jurisdiction since there are no "sales" in interstate commerce. I fully appreciate that we differ in this regard. However, should additional charges be brought under the Agency's authority, [REDACTED] will need to have all its available defenses, including that of the Fifth Amendment.

We discussed as well my client's willingness to agree to discontinue the milk shipments which appear to be the basis of FDA's assertion of jurisdiction, possibly including, on a forward-looking basis, facility inspections to verify that the activity which would invoke FDA jurisdiction is no longer occurring. We offer this method of settlement in lieu of a current inspection, so that my client would have the assurance of settling the past without the risk of further legal exposure.

As you can appreciate, in view of this proposal to settle, any current inspection would appear to be calculated not to achieve the goal of stopping interstate

ATT "I"

shipping, but would appear to point only to the goal of creating other legal risks for [REDACTED]. Hence if we cannot agree to a settlement, [REDACTED] has little choice but to assert its Fifth Amendment rights going forward, together with all other available legal defenses.

You indicated that you would discuss these matters further with your clients. Please contact me this afternoon or tomorrow via cellphone if necessary: 734.646.6091.

Thank you for your courtesies and the ability to discuss these matters frankly.

Very truly yours,

Stephen Bemis, Esq.
6500 Jennings Road
Ann Arbor, MI 48105
P-31599 Michigan

ATTACHMENT J

ATT "J"

From: "Mendoza, Melissa" <Melissa.Mendoza@fda.hhs.gov>
Subject: **RE: ASSERTION OF FIFTH AMENDMENT RIGHTS AND SETTLEMENT PROPOSAL**
Date: March 26, 2010 3:25:58 PM EDT
To: "Steve Bemis" <stbemis@charter.net>
Cc: "Barber, Steven" <Steven.Barber@fda.hhs.gov>, "Pawlowski, Tina M" <Tina.Pawlowski@fda.hhs.gov>

Mr. Bemis:

Thank you for your email. As we have discussed, your client, [REDACTED] refused to allow FDA investigators to inspect the [REDACTED] facility on March 23, 2010. [REDACTED] referred the investigators to you and explained that he would allow an inspection if you so advised. Yesterday morning during our telephone conversation, I explained FDA's authority to inspect the facility pursuant to 21 U.S.C. § 374(a), and I asked you whether you would advise your client to permit FDA to inspect the [REDACTED] facility or whether FDA would need to involve the court. At this point, FDA understands that you have not advised, and do not intend to advise, your client to permit such an inspection. If this is a misunderstanding, and your client will permit an FDA inspection without court intervention, please confirm this as soon as possible.

I am confused about your references to the Fifth Amendment, because FDA is not seeking to interrogate your client; rather, the agency seeks to enter and inspect the [REDACTED] facility to determine whether your client has violated and/or is violating the Federal Food, Drug, and Cosmetic Act ("FDCA") and/or the Public Health Service Act ("PHSA"). If violations are found, FDA could initiate regulatory enforcement actions.

In our second telephone conversation yesterday, you asked whether your client was the subject of a criminal investigation. I told you that I am not aware of an ongoing criminal investigation and would not be able to disclose such information. Please keep in mind that I cannot make representations on behalf of FDA or any other federal or state agency in this regard.

We acknowledge your client's offer to enter into a legally binding agreement, or consent decree entered by the court, which would provide that your client permanently discontinue conduct violative of the FDCA and PHSA. FDA would consider entering into a consent decree if it includes all of the relief that the agency believes is necessary. Among other standard provisions, a decree would restrain and enjoin your client from directly and/or indirectly introducing or

ATT "J"

delivering raw milk or raw milk products in interstate commerce, and require your client to shut down his facility until he can demonstrate compliance with the FDCA and PHSA, maintain records regarding the sale and/or distribution of all raw milk or raw milk products, revise the labeling of such products, and permit FDA to inspect [REDACTED] facility to assure ongoing compliance with the FDCA and PHSA. But please understand that FDA cannot, in the context of such a decree or otherwise, make commitments regarding any additional legal action, on its own belief or that of other federal or state agencies.

If your client is interested in resolving this matter through a consent decree, please contact me. In the meantime, however, please let me know by close of business today whether [REDACTED] will permit FDA investigators to conduct an inspection of [REDACTED] facility. We consider this to be a time-sensitive public health matter.

I can be reached at (301) 827-4803.

Thank you for speaking to us yesterday.

Melissa Mendoza

-----Original Message-----

From: Steve Bemis [mailto:stbemis@charter.net]

Sent: Thursday, March 25, 2010 12:19 PM

To: Mendoza, Melissa; Barber, Steven; Pawlowski, Tina M

Subject: ASSERTION OF FIFTH AMENDMENT RIGHTS AND SETTLEMENT PROPOSAL

DELETED (SEE ATT "I")

ATTACHMENT K

ATT "K"

From: Steve Bemis <stbemis@charter.net>
Subject: **RE: ASSERTION OF FIFTH AMENDMENT RIGHTS AND SETTLEMENT PROPOSAL**
Date: March 26, 2010 4:51:30 PM EDT
To: "Mendoza, Melissa" <Melissa.Mendoza@fda.hhs.gov>
Cc: "Pawlowski, Tina M" <Tina.Pawlowski@fda.hhs.gov>, "Barber, Steven" <Steven.Barber@fda.hhs.gov>

Dear Ms. Mendoza:

Unfortunately, I have had only a short time to read and evaluate your memo of a few hours ago (received while I was at lunch and just opened), and given the timing of its transmission, it is unreasonable to set a deadline of less than two hours for our response. As I mentioned earlier, my client [REDACTED] does not have normal ready access to a telephone, and internet access does not exist. I have had a message for him to call me, on another issue, for more than an hour and a half and that call has not been returned, so counselling him yet this afternoon to meet your deadline is not possible. As well, I wish to consult with other lawyers concerning aspects of your communication. In the circumstances, I will not be able to respond until the close of business Monday.

That said, I wish to clarify, that in our first call yesterday morning I said my recommendation might be that [REDACTED] not permit the inspection, but the purpose of our discussion was for us to evaluate your position, and for you to evaluate our proposal for a consent agreement which I first suggested. In that first call you explicitly said the FDA did not consider my client's two assertions of the need for a search warrant to be refusals, nor would you do so until and unless a third attempt for an inspection met with the same response. I believe we are now discussing that third request.

Second, with all due respect, it is clear that production of documents and other physical things, the taking of samples and indeed the inspection itself would clearly raise Fifth Amendment issues (e.g., not limited to speech or testimony, as you suggest) where, as here, we argue the Agency's lack of jurisdiction due to the private nature of the underlying agreements, the legal effect of which is that there is no "sale" in interstate commerce as defined in the FDCA, and hence no jurisdiction for the FDA. Clearly, if it comes to pass that we cannot agree on a satisfactory resolution of potential civil and criminal risks to [REDACTED] as I said earlier, his rights under the Fifth Amendment will need to remain intact. It is for this reason that we view the Fifth as potentially critical for the preservation of his rights.

ATT "K"

Our consideration of these matters is of course complicated by the Agency's apparent position that it is willing to offer no relief from any other enforcement actions. We believe that the offer of a voluntary resolution through agreement should afford significant enticement for the Agency's more favorable consideration of these aspects of a potential settlement. We will need to consider this further in consultation with the client, among other issues.

Finally, it would be helpful for any further discussion if you would elaborate on what you may consider the proper scope of an inspection. The FDA personnel, when they visited Tuesday, made it clear to [REDACTED] that they would inspect records. As I read 21 U.S.C. 374(a), farms are exempted from records inspection.

We continue to look forward to discussing this matter with you during the day Monday.

Thank you.

Steve Bemis

DELETED (SEE ATT "I" + "J")

ATTACHMENT L

ATT "L"

From: Steve Bemis <stbemis@charter.net>
Subject: **REQUEST FOR INSPECTION**
Date: March 28, 2010 4:38:47 PM EDT
To: melissa.mendoza@fda.hhs.gov, steven.barber@fda.hhs.gov,
tina.pawlowski@fda.hhs.gov
Bcc: FTCLDF President Pete Kennedy - <pete@ftclfd.org>, "David Cox G."
<dcoxlaw@columbus.rr.com>, rdklein <rdklein@net-link.net>

Dear Ms. Mendoza, Mr. Barber and Ms. Pawlowski: At the time we exchanged emails on Friday, I was not aware (although I assume that you were) of the report of campylobacter positives of some kind in milk which may have come from [REDACTED] ([REDACTED]). Following our email exchange Friday afternoon, and prior to learning of these latest reported tests, I had an opportunity to speak further with [REDACTED].

We continue to dispute the jurisdiction of the FDA over the private arrangements under which [REDACTED] has supplied raw milk.

However, I am authorized to notify you that effective immediately, [REDACTED] [REDACTED] has terminated all supply of raw milk and raw milk products out of the state of Indiana.

If you feel in these circumstances that you still need an investigation of [REDACTED] [REDACTED] under the authority of 21 U.S.C. 374(a), upon FDA's proper presentation of credentials and notification, [REDACTED] has authorized me to say that he will not refuse such an inspection.

Please contact me at your earliest convenience so that we may discuss details of such an inspection.

Thank you.

Stephen Bemis, Esq.
(cell) 734.646.6091

CERTIFICATE OF SERVICE

I hereby certify that on 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:

MARTHA A. FAGG
Assistant United States Attorney
600 4th Street, Suite 670
Sioux City, IA 51101
712-255-6011
712-252-2034 (fax)
martha.fagg@usdoj.gov
usao.ian-civ-dc-sc@usdoj.gov

ROGER GURAL
Trial Attorney
Office of Consumer Litigation
Department of Justice
Civil Division
P.O. Box 386
Washington, D.C. 20044
202-307-0174
202-514-8742 (fax)
roger.gural@usdoj.gov

/s/ David G. Cox
David G. Cox