UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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IN RE: PET FOOD PRODUCTS LIABILITY LITIGATION	Civil Action No. 07-2867 (NLH)
	MDL Docket No. 1850 (All Cases)
THIS DOCUMENTS RELATES TO:	The Honorable Noel L. Hillman
ALL CASES	

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR ISSUANCE OF ORDER TO SHOW CAUSE FOR AN ORDER ALLOWING THE DESTRUCTION OF RECALLED WHEAT GLUTEN, RECALLED RICE PROTEIN CONCENTRATE AND OTHER INGREDIENTS ALLEGEDLY CONTAINING MELAMINE BEING STORED BY DEFENDANTS IN THE POSSESSION OF SUCH INGREDIENTS

Plaintiffs, on behalf of themselves and the certified Class (collectively, the "Class Plaintiffs"), by and through their undersigned Co-Lead and Liaison Counsel, respectfully submit the following response to Defendants' Motion for Issuance of Order to Show Cause Allowing the Destruction of Recalled Wheat Gluten, Recalled Rice Protein Concentrate and Other Ingredients Allegedly Containing Melamine Being Stored by Defendants in the Possession of Such Ingredients (the "Motion to Destroy Evidence") [D.E. 317]. Class Plaintiffs submit this response to advise the Court of certain concerns raised by Defendants' proposed course of action.

I. PRELIMINARY STATEMENT

Class Plaintiffs do not, in any way, intend to be obstructionist or unreasonable.

Unfortunately, two sets of objectors have appealed, [D.E. 277, 279], this Court's order granting final approval to a landmark settlement [D.E. 272, 273], leaving a final judgment in this case and overdue relief to approximately 25,000 pet owner claimants hanging in the balance. Although Class Plaintiffs are confident that the Third Circuit will affirm this Court's decision, with this unknown, Class Plaintiffs cannot agree at this time to the wholesale destruction of evidence in

this case, as requested by Defendants. This is particularly so given that the proposed destruction of the evidence: (a) requires a modification of prior orders of this Court; (b) is not supported by the opinions of Defendants' own statistical expert, Dr. George P. McCabe ("Dr. McCabe"), regarding the retention and sampling of wheat gluten and work-in-progress product; (c) is not based on any vetting of the Food and Drug Administration's ("FDA") sampling and testing plan of wheat gluten as reliable; and (d) calls for the destruction of rice protein concentrate, the testing and sampling of which has *never been evaluated* by any expert in this case or in any prior motion by Defendants.

Accordingly, while Class Plaintiffs are mindful that storing ingredients and product with evidentiary value in civil litigation may be costly, Defendants' motion is premature and contrary to the standards previously offered by Defendants' own expert. Until the final approval order is affirmed by the Third Circuit, a ruling on the Defendants' Motion to Destroy Evidence should be deferred. If the Court allows for the destruction of raw ingredients, Defendants should be ordered to follow the sampling and retrieval plans outlined by Dr. McCabe, consistent with this Court's previous Order and the prior agreement reached by Class Plaintiffs and Defendants.

II. ARGUMENT

There are four independent reasons why Defendants' Motion to Destroy Evidence should be deferred at this time. They are as follows:

A. Reason #1: Defendants' Proposed Destruction of Evidence Plan Contravenes This Court's Prior Order Regarding Wheat Gluten and Work-In-Progress and Nothing Has Changed

On December 11, 2007, after several months of arm's-length negotiations between counsel for Defendants, Co-Lead Counsel for Class Plaintiffs, and their respective statistical

experts, ¹ Defendants filed an Unopposed Motion to Limit the Retention of Organized Recalled Product, Raw Wheat Gluten and Unorganized Inventory (the "Evidence Retention Motion") [D.E. 103]. In support of the motion, Defendants submitted a Declaration of Dr. McCabe, [D.E. 103-42], which, among other things: (a) identified a specific retrieval and sampling plan, agreed to by Dr. Jewell, "to preserve certain products which will later be tested to determine the percent of contamination, if any, in the original populations" [*id.*, at p. 2, ¶ 2]. As noted by Dr. McCabe, Defendants intended only for "three types of product to be sampled: "recalled pet treats and food stored in cans, bags and pouches" (*i.e.*, organized recalled product); "recalled raw wheat gluten;" and "work-in-progress" in the possession of Del Monte [*id.*, at p. 2, ¶ 4]. The rice protein concentrate Defendants now seek to destroy was not part of Dr. McCabe's opinion.

On December 18, 2007, this Court entered an Order Granting Defendants' Unopposed Motion to Limit the Retention of Organized Recalled Product, Raw Wheat Gluten and Unorganized Inventory (the "12/18/07 Order") [D.E. 106]. Pursuant to the 12/18/07 Order:

...(1) the ... Defendants may execute the sampling and general retrieval plan for the organized recalled product stored on pallets and/or within cardboard cases as recommended by Dr. George. P. McCabe; (2) Defendants ChemNutra, Del Monte and Menu Foods may execute the sampling and general retrieval plan for the raw wheat gluten as recommended by Dr. McCabe; and (3) Defendant Del Monte may execute the sampling and general retrieval plan for its work-in-progress recipes containing raw wheat gluten as recommended by Dr. McCabe.

... [P]rior to the execution of the sampling and retrieval plans for organized recalled product, raw wheat gluten and work-in-progress recipes, the moving Defendants shall provide Plaintiffs with more specific details concerning the retrieval plans. If Plaintiffs disagree

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¹ Co-Lead Counsel for Class Plaintiffs retained Dr. Nicholas P. Jewell ("Dr. Jewell"), a Professor of Biostatistics & Statistics at the School of Public Health & Department of Statistics, University of California at Berkeley. Dr. Jewell's primary focus was to opine on the propriety of sampling and retrieval plans offered by Defendants' expert, Dr. McCabe.

with any aspect of the retrieval plans, Plaintiffs or Defendants shall have the right to seek Court intervention. If Plaintiffs and Defendants agree conceptually on the specifics of the retrieval plan, Defendants shall provide Plaintiffs with a copy of the more detailed retrieval plans, and Plaintiffs shall have the right to review and comment on the details of the retrieval plans within ten (10) calendar days from the date each plan is provided by Defendants. Within the ten-day period, if Plaintiffs agree with the details of the execution of the retrieval plans, they will notify Defendants in writing. Thereafter, the execution of the sampling and retrieval plans may take place. Nothing regarding the details of the retrieval plans shall prevent Defendants from immediately starting the disposal of the unorganized inventory.

... Defendants are permitted to dispose of any organized recalled product, unorganized inventory, raw wheat gluten or work-in-progress recipe that is unnecessary to implement or execute Dr. McCabe's sampling and retrieval plans.

[*Id.*, at pp. 1-2].

Defendants never "provide[d] Plaintiffs with more specific details concerning the retrieval plans" for organized recalled product, wheat gluten or work-in-progress. Indeed, Defendants appear to have done nothing to prepare, execute or implement the sampling and retrieval plans designed by Dr. McCabe. Now – nearly sixteen (16) months after the Court's December 18, 2007 Order – Defendants have decided that following Dr. McCabe's retention and sampling plans and complying with this Court's Order is unnecessary and too costly. *See* Motion to Destroy Evidence at 3-4, 6. As noted below, contrary to the retention and sampling plans devised by Dr. McCabe and approved by Dr. Jewell and ordered by this Court, Defendants now seek to destroy *all of the evidence* consisting of recalled raw wheat gluten, raw rice protein concentrate and work-in-progress recipes containing melamine, leaving none of it available for testing and evidentiary purposes. *See id.*, at pp. 1-2; *see also* Proposed Order Allowing for the Destruction of Wheat Gluten, etc., [D.E. 318], at p. 1.

Nothing has changed since this Court's 12/18/07 Order which would provide good cause for deviating from it or Dr. McCabe's detailed retention and sampling plans at this time.

Although this Court granted final approval to the class settlement, two appeals by objectors from that approval are pending in the Third Circuit. As a result, it is premature to permit Defendants to destroy potential evidence in this case. However, should the Third Circuit affirm final approval, judgment would become "final" and these evidentiary issues would become moot to Class Plaintiffs.²

B. Reason #2: Defendants' Proposed Destruction of the Evidence Contravenes Their Own Expert's Sampling Plans for Wheat Gluten and Work-In-Progress

The McCabe Declaration [D.E. 103-42] submitted in connection with Defendants' Evidence Retention Motion [D.E. 103] "identif[ied] a 'sampling plan' . . . to preserve certain products which will later be tested to determine the percent of contamination, if any, in the original populations." [Id., at p. 2, ¶ 2]. Dr. McCabe's sampling plan also

[E]nsure[d] that test results on the samples, when analyzed by a statistician, [would] enable accurate inferences to be drawn about the distribution of the percent of contamination in the original populations. Specifically, these results will be used to estimate the mean percent of contamination, plus or minus two standard deviations, in the original populations. In effect, [Dr. McCabe] [has] been asked to answer the statistical question – how much product does each Defendant need to retain in order for the parties and the Court to have a sufficient sample that is representative of the whole in a statistically significant manner.

[*Id.*]. Dr. McCabe then opined that 500 computer-generated random samples of wheat gluten per batch number be retrieved, [*id.*, at p. 9, ¶26], and that 500 random samples of work-in-progress

² Class Plaintiffs take no position on the impact the proposed destruction might have on other litigants.

per recipe be retrieved randomly, "evenly distributing the 500 samples across all totes." [*Id.*, at p. 9, ¶ 27]. Finally, Dr. McCabe stated:

Upon approval of this sampling plan, I will devise a specific, detailed retrieval plan for each Defendant to ensure a random sampling is retrieved for each SKU date, batch or recipe that will identify each case, sample and/or unit to be retrieved and retained. I intend to be personally involved in the execution of each Defendant's sampling and retrieval plan to ensure that the execution is conducted in an acceptable manner so that I can attest to the results at a later time.

[Id., at pp. 9-10, ¶ 28]. Importantly, Dr. McCabe was only able to opine on and identify "the samples to be taken" and had to "defer to a person with knowledge of the testing required with respect to the amount of sample necessary for testing purposes." [Id., at p. 9, ¶¶ 26-27].

Now, Defendants seek to abandon their own expert's detailed opinions regarding the appropriate retention and sampling plan for reliably testing wheat gluten and work-in-progress and are instead advocating for the destruction of such ingredients altogether. Putting aside the propriety of the FDA's testing, discussed below, Defendants have not justified the modification of Dr. McCabe's proposed plan at this time.

C. Reason #3: There Has Been No Vetting of the FDA's Sampling and Testing to Render It Reliable for Use In This Case

Class Plaintiffs respectfully remind the Court that, on September 5, 2008, shortly before the final approval hearing, Defendant ChemNutra, Inc. ("ChemNutra") filed a Motion to Destroy Retained Wheat Gluten, [D.E. 194], which sought approval from this Court for the destruction of *all* wheat gluten stored by ChemNutra:

because: (1) the FDA has already conducted a reliable, independent and valid sampling and testing of ChemNutra's Wheat Gluten . . .; (2) the FDA has requested that ChemNutra destroy the recalled Wheat Gluten in its possession due to public health and safety concerns . . .; (3) the substantial financial burden and costs associated with retaining ChemNutra's Wheat Gluten . . .; (4) both the FDA and US Attorneys office support ChemNutra's request to

destroy its Wheat Gluten; [and] (5) the destruction would be done in accordance with and under the supervision of the FDA.

[D.E. 194, at pp. 1-2].

On September 19, 2008, Plaintiffs filed their Opposition to ChemNutra's Motion to Destroy Its Inventory of Wheat Gluten [D.E. 231]. Class Plaintiffs hereby incorporate the arguments raised in their opposition brief herein, summarized as follows:

- ChemNutra did not seek to preserve any samples of product for independent statistical sampling and offered no evidence or expert affidavits (including from Dr. McCabe) that the FDA sampling was adequate for evidentiary purposes or would otherwise be admissible in this case;
- The FDA never sought to intervene in this case to seek relief from this Court regarding destruction of the wheat gluten;
- The pendency of final approval of the class settlement militated against granting the extraordinary relief requested by ChemNutra; and
- The law cited by ChemNutra did not support the destruction of all available
 evidence, but rather supported the retention of statistically representative samples.

[D.E. 231, at pp. 1-6].

This Court never ruled on ChemNutra's motion.³ The circumstances underlying that motion and Plaintiffs' opposition are unchanged. There is still no evidence before the Court that

³ Indeed, at the final approval hearing on October 14, 2008, this Court inquired as to whether Plaintiffs and ChemNutra could agree to the destruction of wheat gluten stored in a warehouse in Bloomsburg, Pennsylvania. *See* 10/14/08 Fairness Hearing Transcript, at pp. 98-100. Based on ChemNutra's representations to Co-Lead Counsel and this Court that it "did not sell, distribute or supply . . . to any person or entity and that, therefore, no pets would have been exposed to food containing ChemNutra supplied wheat gluten from this batch number," a Stipulation and [Proposed] Consent Order to Destroy ChemNutra's Retained Wheat Gluten Stored in the

the FDA's sampling and testing of ChemNutra's wheat gluten was reliable or would withstand evidentiary challenge in litigation. Defendants' contention that the results from the FDA's sampling plan and testing are "reliable and valid" is without support. [D.E. 194, at p. 4].

In addition, contrary to Defendants' contention, [D.E. 317, at p. 3], the FDA's sampling and testing plan does not appear at all to comport with Dr. McCabe's sampling plan. *Compare* FDA Report attached as Exhibit B to Declaration of Karen M. Firstenberg [D.E. 320-3], *with* McCabe Declaration [D.E. 103-42]. Such a discrepancy raises concerns about the applicability, and perhaps reliability and validity, of the FDA plan. Certainly the FDA plan has not been vetted and approved by this Court, as was Dr. McCabe's plan.

Finally, notwithstanding the "FDA and USDA's comprehensive investigation" surrounding the pet food recall at issue in this case, 4 and the fact that the FDA specifically regulates pet food under the Federal Food, Drug, and Cosmetic Act, 5 it is telling that the FDA has never sought to intervene under Fed. R. Civ. P. 24(a) or (b) for the limited purpose of seeking the destruction of contaminated wheat gluten or other ingredients, nor sought to appear as *amicus curiae* in support of either ChemNutra's initial motion or Defendants' current Motion to Destroy Evidence. *See Liberty Lincoln Mercury, Inc. v. Ford Marketing Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993) ("[P]ermitting persons to appear in court . . . as friends of the court . . . may be advisable where third parties can contribute to the court's understanding.") (citing *Harris v. Pernsley*, 820 F.2d 592, 603 (3d Cir. 1987)).

Bloomsburg, Pennsylvania Warehouse was executed by Co-Lead Counsel and ChemNutra's counsel, and approved by this Court [D.E. 268].

⁴ See http://www.fda.gov/oc/opacom/hottopics/petfood.html (last visited, Mar. 24, 2009).

⁵ See http://www.fda.gov/cvm/petfoods.htm (last visited, Mar. 24, 2009).

D. Reason #4: Neither the FDA Nor Any Expert Has Ever Addressed the Retention, Sampling or Destruction of Rice Protein Concentrate

Although Defendants have acknowledged that the FDA only conducted testing of contaminated wheat gluten, [D.E. 317, at pp. 3-4], and that Dr. McCabe only opined on sampling plans for organized recalled product, wheat gluten and work-in-progress, [id., at p. 1], Defendants nevertheless include "rice protein concentrate" with the other ingredients that they seek to destroy. The record before the Court provides no basis for permitting the destruction of raw rice protein concentrate. The parties have conducted no testing of rice protein concentrate and no biostatistician, or any other expert, has rendered an opinion regarding an appropriate and statistically relevant sampling plan for raw rice protein concentrate, as was performed with respect to raw wheat gluten and work-in-progress. Again, while destruction of rice protein concentrate may very well be appropriate upon the resolution of the two pending appeals, such destruction is premature at this time based on this record.

III. CONCLUSION

For the reasons stated above, this Court should defer its ruling on Defendants' Motion for Issuance of Order to Show Cause for an Order Allowing for the Destruction of Recalled Wheat Gluten, Recalled Rice Protein Concentrate and Other Ingredients Allegedly Containing Melamine Being Stored by Defendants in the Possession of Such Ingredients until the Third Circuit affirms the final approval order.

DATED: April 3, 2009 Respectfully submitted,

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