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Civil Administration
K. PERMSAP

IN THE COURT OF COMMON PLEAS
PHILADELPHIA, COUNTY, PENNSYLVANIA

IN RE: DENTURE ADHESIVE CREAM LITIGATION

MASS TORT PROGRAM

June Term, 2009

No. 4534

ORDER

AND NOW, this ____ day of _____ 2010, upon consideration of the Plaintiffs' Responses and Memorandum of Law in Support of Plaintiffs' Responses to the Defendants' The Procter & Gamble Distributing LLC and The Procter & Gamble Manufacturing Company Preliminary Objections to Plaintiffs' Master Long Form Complaint, and Defendants' moving papers, it is hereby ORDERED and DECREED that Defendants' Preliminary Objections are denied in their entirety.

BY THE COURT:

_____
MOSS, J.

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Control No.: 09112680

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IN THE COURT OF COMMON PLEAS
PHILADELPHIA, COUNTY, PENNSYLVANIA

IN RE: DENTURE ADHESIVE CREAM LITIGATION	**: June Term, 2009**
MASS TORT PROGRAM	**: No. 4534**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' RESPONSES TO THE DEFENDANTS' THE PROCTER & GAMBLE MANUFACTURING COMPANY AND THE PROCTER & GAMBLE LLC PRELIMINARY OBJECTIONS TO PLAINTIFFS' MASTER LONG FORM COMPLAINT

Plaintiffs, by and through their undersigned counsel, hereby file Responses to the Defendants' The Procter & Gamble Manufacturing Company and The Procter & Gamble LLC (the "P&G Defendants") Preliminary Objections to Plaintiffs' Master Long Form Complaint ("Master Complaint" or "Complaint") and in support thereof respond as follows:

1. Admitted to the extent it is consistent with Plaintiffs' allegations in paragraph 14 of the Master Complaint.

2. Admitted to the extent it is consistent with Plaintiffs' allegations in paragraphs 2-5 of the Master Complaint.

3. Admitted to the extent it is consistent with Plaintiffs' allegations in paragraph 11

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of the Master Complaint.

4. Denied. The Master Complaint sets forth claims, *e.g.*, that none of the Fixodent product materials (including the boxes Fixodent is sold to customers in or the tubes of Fixodent itself) provide any information to consumers that Fixodent contains zinc, let alone that using Fixodent can result in zinc poisoning, copper deficiency and/or neurological injuries. In any event, Paragraphs 43 and 44 of the Master Complaint are in writing and speak for themselves.

5. Admitted in part to the extent it is consistent with Plaintiffs' allegations in paragraphs 50-53 of the Master Complaint about GlaxoSmithKline ("GSK"). Denied in part as to Fixodent and the P&G Defendants. The Master Complaint alleges that historically, since P&G added zinc to its Fixodent products, P&G has known about the link between excessive zinc exposure, copper deficiency and neurological injuries through generally accepted scientific literature.[1] *Complaint* ¶¶ 60 and 61. The Master Complaint further alleges that as early as 2007 there were at least three published scientific peer reviewed journal articles specifically linking denture adhesives, including Fixodent, to zinc poisoning, copper deficiency and neurological injuries. *Id.* ¶¶ 67-69. Despite generally accepted medical literature and published peer reviewed journal articles establishing a specific link, P&G has failed to provide any information to consumers that Fixodent contains zinc, let alone that using Fixodent can result in zinc poisoning, copper deficiency and/or neurological injuries. *Id.* ¶¶ 16, 43.

6. Neither admitted nor denied.

7. Denied. Plaintiffs' Master Complaint alleges that Defendants were aware

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1 The P&G Defendants prematurely move to dismiss Plaintiffs' punitive damages claims as discovery is ongoing and Plaintiffs are still in the process of reviewing documents. At the time the Master Complaint was filed, the P&G Defendants produced less than one-third of the documents they anticipate producing in this litigation. *See* Exhibit A (Oct. 28, 2009 Ltr to Melissa Korfhage re: P&G Production Deficiencies); *Kiesel v. Lehigh Valley Eye Center P.C.*, 2006 WL 4069448, *435 (Pa.Com.Pl. 2006) (holding that dismissing punitive damages claim is premature if plaintiff has not been given an opportunity to develop proper record).

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through, *inter alia*, published scientific peer reviewed journal articles that specifically linked Fixodent products to zinc poisoning and copper deficiency, and medical literature about the adverse effects in humans when exposed to excessive amounts of zinc. *Id.* ¶¶ 60, 61, 67, 68. Indeed, P&G's own production of documents to date, confirms P&G's knowledge about the ramifications of excessive zinc exposure. *Id.* ¶ 43; *see also* (medical journal articles dating back to the early 1980s produced by P&G showing that excessive zinc exposure results in copper deficiency and neurological injuries).[2]

8. Denied. Plaintiffs' Master Complaint alleges that Defendants were aware through, *inter alia*, published scientific peer reviewed journal articles that specifically linked Fixodent products to zinc poisoning and copper deficiency, and medical literature about the adverse effects in humans when exposed to excessive amounts of zinc. Complaint ¶¶ 60, 61, 67, 68. Indeed, P&G's own production of documents to date confirms P&G's knowledge about the ramifications of excessive zinc exposure.[3] Moreover, the 2009 article titled "*Myelopolyneuropathy and pancytopenia due to copper deficiency and high zinc levels of unknown origin II. The denture cream is a primary source of excessive zinc*" ("Hedera article") specifically cites a 2007 article that reported the connection between denture fixatives as a possible source of zinc poisoning and copper deficiency. Hedera P, et. al, *Myelopolyneuropathy and pancytopenia due to copper deficiency and high zinc levels of unknown origin II. The denture cream is a primary source of excessive zinc*, Neurotoxicology, August 2009, attached

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2 P&G has designated the articles (along with nearly all other documents in its productions) "CONFIDENTIAL SUBJECT TO COURT ORDER" even though the articles are publicly available documents and, therefore, Plaintiffs cannot attach them for the Court to oppose P&G's Preliminary Objections). Plaintiffs are providing P&G with Notice under the Court's protective order that they intend to move to unseal these and other documents that P&G has wrongly designated "CONFIDENTIAL" that support Plaintiffs' opposition to P&G's Preliminary Objections.

3 *See* footnote 2 *supra*.

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hereto as Exhibit B; *see* Complaint ¶ 69.

9. Denied. Plaintiffs' Master Complaint cites to studies linking Fixodent use to neuropathy. Complaint ¶¶ 67-68. In particular, the Nations article studied four patients who chronically and excessively used Fixodent and/or Poligrip. The Abstract states: "**Conclusion:** Denture cream contains zinc, and chronic excessive use may result in hypocupremia [copper deficiency] and serious neurologic disease." S.P. Nations, Boyer, et. al, *Denture cream: An Unusual Source of Excess Zinc Leading to Hypocupremia and Neurologic Disease*, Neurology, June 2008, pp. 639-643 (emphasis in original). Moreover, the Hedera article reports on a study of eleven patients, at least four of whom used Fixodent. *See* Exhibit B at 1. The Hedera article concludes:

> In summary, poorly fitting dentures requiring large amounts of denture cream to provide a sufficient seal appear to be the common characteristics of patients with idiopathic hypocupremia, hyperzincemia, bone marrow suppression and a combination of polyneuropathy with spinal cord degeneration. Patients presenting with this constellation of neurologic and hematological signs need to be immediately screened for abnormal blood copper and zinc levels, and the use of large amounts of denture cream. ***It appears their disease is fully explained by denture cream use.***

Id. at 4 *(emphasis added)*; Complaint ¶ 68. The Nations and Hedera articles conclude that denture creams with zinc, including Fixodent, can cause copper deficiency and neuropathy. Despite this publicly available information that is imputed to P&G, P&G has outrageously failed to tell consumers that Fixodent contains zinc and that using the product can lead to zinc poisoning, copper deficiency and permanent and profound neurological injuries. *Id.* ¶¶ 16, 43. For months and sometimes years, Plaintiffs have gone undiagnosed or have been unable to find the source of their excessive zinc exposure (which appeared in blood serum and urine tests), while the P&G Defendants knowingly have stood silent about the zinc in its products. *Id.* ¶¶ 69-70. The law is clear that if there is evidence that the defendant "realized the risk and acted in conscious disregard or

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indifference to it," there is a sound basis for imposing punitive damages. *See Burke v. Maasen*, 904 F.2d 178, 182 (3rd Cir. 1990)

10. Admitted to the extent it is consistent with Plaintiffs' allegations in paragraphs 67-68 of the Master Complaint.

11. Denied. Plaintiffs' Master Complaint states specific facts and evidence that support their claims for punitive damages including that the P&G Defendants knew about the link between chronic exposure to excess zinc and injury to humans, including profound, irreversible neurological damage caused by hyperzincemia and hypocupremia through general and specific scientific evidence. Despite this clear and undeniable knowledge, the P&G Defendants have still failed to act or to warn the unknowing public about the dangers of Fixodent. Complaint ¶¶ 60, 61, 67-70.

COUNT I

ANY AND ALL ALLEGATIONS OF PUNITIVE DAMAGES, RECKLESSNESS, CARELESS, WILLFUL, WANTON, KNOWING, INTENTIONAL, AND OUTRAGEOUS CONDUCT DIRECTED TO THE P&G DEFENDANTS ARE SUFFICIENTLY PLED IN THE PLAINTIFFS' MASTER COMPLAINT AND THEREFORE SHOULD NOT BE DISMISSED

12. Plaintiffs' incorporate their response to paragraphs 1 through 11 as if the same were set forth at length herein.

13. Admitted but by way of further answer, the material facts set forth in Plaintiffs' Master Complaint are stated in a concise and summary form. Preliminary Objections should only be sustained in cases that are free and clear from doubt. *Bower v. Bower*, 611 A.2d 181, 182 (Pa. 1992). Any doubt should be resolved against the objecting party. *Koken v. Steinberg*, 825 A.2d 723, 726 (Pa. Cmwlth. 2003). In reviewing preliminary objections, facts that are well-pleaded, material and relevant will be considered as true, together with such reasonable

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inferences as may be drawn from such facts. *Mellon Bank, N.A. v. Fabinyi*, 650 A.2d 895, 899 (Pa. Super. 1994).

14. Admitted but by way of further answer, Plaintiffs' Master Complaint sets forth facts that are legally sufficient to establish a right to relief. Preliminary Objections should only be sustained in cases that are free and clear from doubt. *Bower*, 611 A.2d at 182. Any doubt should be resolved against the objecting party. *Koken*, 825 A.2d at 726. In reviewing preliminary objections, facts that are well-pleaded, material and relevant will be considered as true, together with such reasonable inferences as may be drawn from such facts. *Mellon Bank, N.A.*, 650 A.2d at 899.

15. Admitted but by way of further answer, Plaintiffs' Master Complaint sets forth facts that are legally sufficient to establish a right to relief. Preliminary Objections should only be sustained in cases that are free and clear from doubt. *Bower*, 611 A.2d at 182. Any doubt should be resolved against the objecting party. *Koken*, 825 A.2d at 726. In reviewing preliminary objections, facts that are well-pleaded, material and relevant will be considered as true, together with such reasonable inferences as may be drawn from such facts. *Mellon Bank, N.A.*, 650 A.2d at 899.

16. Denied. The Master Complaint alleges facts concerning the P&G Defendants' culpable state of mind, which is a sufficient basis for a punitive damages claim. *McDaniel v. Merck*, 533 A.2d 436, 447-48 (Pa. Super. 1987). The Master Complaint alleges that the P&G Defendants knew about the correlation between excessive zinc exposure with Fixodent use, copper deficiency and neurological problems and that they failed to inform consumers that Fixodent contains zinc, let alone inform them that use of Fixodent can result in zinc poisoning, copper deficiency and/or neurological disorders. *See, e.g.*, Complaint ¶¶ 59, 60, 61, 67-69. Indeed, when there is evidence that the defendant "realized the risk and acted in conscious

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disregard or indifference to it," there is a sound basis for imposing punitive damages. *Burke v. Maasen*, 904 F.2d 178, 182 (3rd Cir. 1990) (applying Pennsylvania law).

17. Admitted that Plaintiffs have pled that Defendants' conduct was "outrageous," "unconscionable," or "wanton" but denied that such allegations are not pled with the requisite specificity. *See, e.g.*, *id.* ¶¶ 59, 60, 61, 67-69.

18. Denied. Plaintiffs have pled a claim for punitive damages with specificity. The Master Complaint alleges that the P&G Defendants knew about the correlation between excessive zinc exposure with Fixodent use, copper deficiency and neurological problems and that they failed to inform consumers that Fixodent contains zinc, let alone inform them that use of Fixodent can result in zinc poisoning, copper deficiency and/or neurological disorders. *See, e.g.*, *id.* ¶¶ 59, 60, 61, 67-69. Under Pennsylvania law, a plaintiff may state a claim for punitive damages by alleging that the defendant had actual knowledge of the risk imposed to the health and welfare of another, and, in the face of that knowledge, acted, or failed to act, in conscious disregard of the risk. *Burke*, 904 F.2d at 182. Therefore, Plaintiffs' Master Complaint complies with both Pennsylvania law and the court's local rules.

19. Denied. Outrageous conduct is an "act done with a bad motive or with a reckless indifference to the interests of others." *McClean v. O'Kelly*, 2001 WL 1846964, *7 (Pa.Com.Pl. 2001). Plaintiffs' Master Complaint alleges facts that rise to the level of "outrageous behavior" or "wanton conduct." The Master Complaint alleges that the P&G Defendants knew about the correlation between excessive zinc exposure with Fixodent use, copper deficiency and neurological problems and that they failed to inform consumers that Fixodent contains zinc, let alone inform them that use of Fixodent can result in zinc poisoning, copper deficiency and/or neurological disorders. *See, e.g.*, ¶¶ 59, 60, 61, 67-69. Further, the Master Complaint alleges that these failures have caused the initial injuries and the continuation of them because Plaintiffs have suffered months and years of poisoning and disabilities that went diagnosed and untreated

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as a result of the P&G Defendants' concealment and failure to disclose the problems with Fixodent. Complaint ¶ 70. Moreover, even assuming *arguendo* that June 2008 is the earliest that the P&G Defendants knew that Fixodent was potentially linked to serious neurological disease, P&G continues to engage in outrageous conduct warranting punitive damages by failing to act or inform the medical community and the general public of these dangers. *See Martin v. Johns-Manville Corp.*, 508 Pa. 154, 494 A.2d 1088, 1097-98 (1985) (plurality opinion); followed by *SHV Coal, Inc. v. Continental Grain Co.*, 526 Pa. 489, 587 A.2d 702, 704-705 (1991) (In Pennsylvania, a punitive damages claim is sustained if there is evidence that: "(1) a defendant had a subjective appreciation of the risk to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk.")

20. Admitted and by way of further answer, a plaintiff with a case sounding in negligence can undertake the additional burden of attempting to prove that a defendant's conduct was not only negligent but also outrageous, necessitating an award of punitive damages. *See Hutchison v. Luddy*, 582 Pa. 114, 870 A.2d 766, 772 (2005).

21. Admitted.

22. Admitted.

23. Denied. A plaintiff with a case sounding in negligence can undertake the additional burden of attempting to prove that a defendant's conduct was not only negligent but also outrageous, necessitating an award of punitive damages. *See Hutchison v. Luddy*, 870 A.2d 766, 772 (2005). In *Hutchison,* the Pennsylvania Supreme Court rejected the Superior Court's conclusion that punitive damages are unavailable, as a matter of law, in a negligent supervision action. Importantly, in reaching its conclusion, the Court noted that there are many leading cases, including *Feld v. Merriam*, 506 Pa. 383, 485 A.2d 742 (1984), that discuss awarding punitive damages in cases sounding in negligence and thus saw no reason to distinguish between actions sounding in negligence versus negligent supervision actions. *See Hutchison*, 870 A.2d at

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772 (2005). Here, Plaintiffs' Master Complaint sufficiently alleges facts to set forth a claim for punitive damages under the negligence, gross negligence and malice causes of action. The Master Complaint alleges the P&G Defendants' knew of the potential for zinc poisoning from Fixodent through: the litany of scientific articles written since as early as 1976 about excessive zinc exposure and resulting copper deficiency and neurological problems; the 2006 lawsuits against GSK, P&G's largest competitor, linking denture adhesives to zinc poisoning; and published scientific peer reviewed journal articles, as early as 2007, linking denture fixatives such as Fixodent with zinc poisoning. Complaint ¶¶ 53, 60, 61, 64, 67-70. Despite this knowledge, unlike GSK, P&G has done nothing to change its labeling on its tubes or packaging to warn consumers that Fixodent contains zinc or of the risk of possible debilitating neurological injuries that can be caused by Fixodent. Complaint ¶ 54. Exhibit C (GSK's current packaging, for example, states that Super Poligrip contains zinc and warns of case reports about the adverse effects of zinc poisoning from denture cream).

24. Admitted.

25. Admitted.

26. Denied. Plaintiffs's Master Complaint alleges that the P&G Defendants knew about the serious neurological injuries its Fixodent products could cause and failed to act and continues to fail to act. Complaint ¶¶ 60, 61, 67-70. This is sufficient to support a claim for punitive damages. *See McDaniel v. Merck*, 533 A.2d 436, 447-48 (Pa. Super. 1987), (holding that manufacturer's failure to act, in face of serious risk of injury to consumers, was sufficient to allow claim for punitive damages). Defendants will be afforded an opportunity, prior to trial, to determine whether Plaintiffs' evidence is sufficient to submit a claim to the jury for punitive damages. *See McClennan v. HMO of Pennsylvania a/k/a HMO PA*, 413 Pa. Super. 128, 604 A.2d 1053, 1061 (Pa. Super. 1992). Defendants' conclusory argument that Plaintiffs fail to allege facts that warrant the ***imposition*** of punitive damages is simply premature provided that

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discovery is ongoing. *See Kiesel v. Lehigh Valley Eye Center P.C.*, 2006 WL 4069448, *435 (Pa.Com.Pl. 2006) (holding that dismissing punitive damages claim would be premature if plaintiff has not been given opportunity to develop proper record).

27. Denied. There are at least dozens of scientific articles that P&G has produced discussing the connection between excessive zinc consumption, copper deficiency and neurological problems, dated as early as 1976. More specifically, the Spinazzi 2007 article, the Nations June 2008 and the Hedera September 2009 journal articles specifically connect denture fixatives, including Fixodent, to zinc poisoning, copper deficiency and neurological injuries. Despite this knowledge, P&G continues to market and sell Fixodent without ***any*** notice that Fixodent contains zinc or any warnings about the potential for zinc poisoning. Complaint ¶¶ 67-69. As such, the Master Complaint sufficiently pleads facts to support a claim for punitive damages and complies with the fact-pleading requirements of Rule 1019(a) of the Pennsylvania Rules of Civil Procedure.

28. Admitted in part. Currently, there are no Nebraska citizens who are Plaintiffs and have sued the P&G Defendants in this litigation. If the situation arises, Plaintiffs agree to address state specific consumer fraud statute issues relating to punitive damages in individual Plaintiff Short Form Complaints, as it has agreed to do with GSK.

29. Admitted in part. Currently, there are no Louisiana, Massachusetts, Washington or New Hampshire citizens who are Plaintiffs and have sued the P&G Defendants in this litigation. If the situation arises, Plaintiffs agree to address state specific consumer fraud statute issues relating to punitive damages in individual Plaintiff Short Form Complaints, as it has agreed to do with GSK.

30. Admitted in part. If the situation arises, Plaintiffs agree to address state specific consumer fraud statute issues relating to punitive damages in individual Plaintiff Short Form Complaints, as it has agreed to do with GSK.

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31. Denied. For the reasons stated above, Plaintiffs' Master Complaint sufficiently pleads facts, if true, would support submitting the issue of punitive damages to a jury. Therefore, Defendants Preliminary Objections should be denied.

WHEREFORE, Plaintiffs' respectfully request that this Honorable Court deny Defendants' Preliminary Objections.

Dated: January 6, 2010

Respectfully submitted,

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IN THE COURT OF COMMON PLEAS
PHILADELPHIA, COUNTY, PENNSYLVANIA

IN RE: DENTURE ADHESIVE CREAM LITIGATION	:	**June Term, 2009**
MASS TORT PROGRAM	:	**No. 4534**

THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' RESPONSES TO THE DEFENDANTS' THE PROCTER & GAMBLE MANUFACTURING COMPANY AND THE PROCTER & GAMBLE LLC PRELIMINARY OBJECTIONS TO PLAINTIFFS' MASTER LONG FORM COMPLAINT

I. INTRODUCTION

Plaintiffs, by and through the undersigned counsel, hereby respond to the Defendants' The Procter & Gamble Manufacturing Company and The Procter & Gamble LLC (the "P&G Defendants") Preliminary Objections to the Master Long Form Complaint ("Master Complaint" or "Complaint"). Defendants contend that Plaintiffs have failed to plead punitive damages with the required specificity for multiple claims. For the reasons set forth herein, Plaintiffs respectfully request that this Honorable Court overrule and deny each and every one of Defendants' Preliminary Objections.

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II. STATEMENT OF QUESTION PRESENTED

QUESTION: Should the P&G Defendants' Preliminary Objections be sustained where Plaintiffs' Complaint fails to meet the pleading requirement of Pennsylvania law to support multiple claims on punitive damages?

SUGGESTED ANSWER: Plaintiffs' Master Complaint sufficiently alleges punitive damages, and, therefore, the P&G Defendants' Preliminary Objections should be denied in their entirety.

II. STATEMENT OF FACTS

Plaintiffs have brought actions against the P&G Defendants and GlaxoSmithKline and related entities ("GSK") alleging that their over-the-counter denture creams with zinc, Fixodent and Super Poligrip, respectively, have caused zinc poisoning, copper deficiency and neurological injuries. Complaint ¶¶ 7, 8, 43. The Master Complaint alleges that the P&G Defendants added zinc to Fixodent in 1990. *Id.* ¶¶ 7, 11. Since that time, the P&G Defendants have marketed and sold Fixodent without listing its ingredients, clear instructions on use or any type of warning that using a certain amount of Fixodent could lead to zinc poisoning, copper deficiency or neurological problems. *Id.* ¶¶ 43, 44.

The Master Complaint further alleges that the P&G Defendants knew through published scientific peer reviewed journal articles at least as early as 2007 that denture fixatives, including Fixodent, could cause zinc poisoning. These articles specifically conclude that Fixodent causes zinc poisoning. *Id.* 67-69. In particular, the Nations article studied four patients who chronically and excessively used Fixodent and/or Poligrip. The Abstract states: "**Conclusion:** Denture cream contains zinc, and chronic excessive use may result in hypocupremia [copper deficiency] and serious neurologic disease." S.P. Nations, Boyer, *et. al*, *Denture cream: An Unusual Source of Excess Zinc Leading to Hypocupremia and Neurologic Disease*, Neurology, June 2008, pp. 639-643) (emphasis in orginal). Moreover, the Hedera article reports on a study of eleven patients, at least four of whom used Fixodent. Hedera P, *et. al*, *Myelopolyneuropathy and*

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pancytopenia due to copper deficiency and high zinc levels of unknown origin II. The denture cream is a primary source of excessive zinc, Neurotoxicology, August 2009, attached hereto as Exhibit B. The Hedera article concludes:

> In summary, poorly fitting dentures requiring large amounts of denture cream to provide a sufficient seal appear to be the common characteristics of patients with idiopathic hypocupremia, hyperzincemia, bone marrow suppression and a combination of polyneuropathy with spinal cord degeneration. Patients presenting with this constellation of neurologic and hematological signs need to be immediately screened for abnormal blood copper and zinc levels, and the use of large amounts of denture cream. ***It appears their disease is fully explained by denture cream use.*** *(emphasis added).* *Id.* at 4, Complaint ¶ 68.

Id. at 4 *(emphasis added);* Complaint ¶ 68. The Nations and Hedera articles conclude that denture creams with zinc, including specifically Fixodent, can cause copper deficiency and neuropathy. Complaint ¶¶ 69-70.

Moreover, the Master Complaint alleges that the P&G Defendants have historic knowledge of the dangers of zinc. *Id.* at 60-61. The P&G Defendants have produced, from their own files, dozens of scientific articles, dating back to as early as 1976 discussing how excessive zinc exposure can lead to copper deficiency and neurological problems.[1] *Id.* ¶ 43. Lastly, the 2006 lawsuits against GSK, P&G's largest competitor, further provided the P&G Defendants with knowledge that denture adhesives with zinc can lead to zinc poisoning. *Id.* ¶¶ 64-65.

Despite this publicly available information that is imputed to P&G, P&G has outrageously failed to tell consumers that Fixodent contains zinc or that using it can lead to zinc poisoning, copper deficiency and permanent and profound neurological injuries. *Id.* ¶¶ 16, 43. For months and sometimes years, Plaintiffs in this litigation have gone undiagnosed or have been

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[1] P&G has designated the articles (along with nearly all other documents in its productions) "CONFIDENTIAL SUBJECT TO COURT ORDER" even though the articles are publicly available documents and, therefore, Plaintiffs cannot attach them for the Court to oppose P&G's Preliminary Objections). Plaintiffs are providing P&G with Notice under the Court's protective order that they intend to move to unseal these and other documents that P&G has wrongly designated "CONFIDENTIAL" that support Plaintiffs' opposition to P&G's Preliminary Objections.

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unable to find the source of elevated zinc in their blood and/or urine tests, while the P&G Defendants knowingly stood silent and as a result the Plaintiffs have suffered greater personal injury and damage. *Id.* ¶¶ 69-70. To date, neither the Fixodent tube nor the box have any mention of zinc, let alone a warning that a certain dosage of Fixodent use could lead to zinc poisoning, copper deficiency, neurological injuries or any other type of adverse health event. *Id.* ¶ 43.

III. STANDARD OF REVIEW

In Pennsylvania, the test for reviewing preliminary objections has been well established:

> Preliminary objections, the end result of which would be dismissal of cause of action, should be sustained only in cases that are free and clear from doubt. The test on preliminary objections is whether it is clear and free from doubt from all the facts pleaded that the pleader will be unable to prove facts legally sufficient to establish his right to relief.

Bower v. Bower, 611 A.2d 181, 182 (Pa. 1992) (citations omitted). Any doubt should be resolved *against* the objecting party. *Koken v. Steinberg*, 825 A.2d 723, 726 (Pa.Cmwlth. 2003). In reviewing preliminary objections, facts that are well-pled, material, and relevant, together with such reasonable inferences as may be drawn from such facts, are considered true. *Mellon Bank, N.A. v. Fabinyi*, 650 A.2d 895, 899 (Pa. Super. 1994).

In this matter, Plaintiffs' have satisfied their burden of pleading facts sufficient to prove their right to relief against the Defendants. Accordingly, Defendants' preliminary objections should be overruled in their entirety.

IV. LEGAL ARGUMENT

A. PLAINTIFFS' MASTER COMPLAINT SUFFICIENTLY PLEADS CLAIMS FOR PUNITIVE DAMAGES

The Master Complaint sets forth well-supported and well-pleaded claims for punitive damages against the P&G Defendants. Under Pennsylvania law, the right to punitive damages is a "mere incident to a cause of action." *Hilbert v. Roth*, 149 A.2d 648, 652 (Pa. 1959); *see also*

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Nix v. Temple University, 596 A.2d 1132, 1138 (Pa. Super. 1991) (stating that "[a] request for punitive damages does not constitute a cause of action in and of itself."). Punitive damages are appropriate where a defendant's conduct is outrageous, either because of an evil motive or because of a reckless indifference to the rights of others. *See Martin v. Johns-Mannville Corp.*, 494 A.2d 1088, 1096 (Pa. 1985).

The Restatement (Second) of Torts Section 908 (2) has been adopted as law in Pennsylvania, and provides:

> Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the right of others. In assessing punitive damages, *the trier of fact* can properly consider the character of the defendant's act, the nature and extent of the harm to the plaintiff that the defendant caused or intended to cause and the wealth of the defendant.

Field v. Philadelphia Electric Co., 565 A.2d 1170, 1182 (Pa. Super. 1989) (quoting the Restatement (Second) of Torts Section 908) (emphasis added). Section 500 of the Restatement (Second) of Torts further refines the perimeter of reckless conduct:

> The actor's conduct is in reckless disregard of the safety of another if he does an act or intentionally fails to act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent.

Martin, 494 A.2d at 1097 (quoting the Restatement (Second) of Torts Section 500 (1965) and noting how it informs Section 908 (2)). Punitive damages are appropriate to provide an additional deterrent for a defendant who is found to have acted in a fashion that is especially egregious. *See G.J.D. v. Johnson*, 713 A.2d 1127, 1129 (Pa. 1998).

When there is evidence that the defendant "realized the risk and acted in conscious disregard or indifference to it," there is a sound basis for imposing punitive damages. *Burke v.*

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Maasen, 904 F.2d 178, 182 (3rd Cir. 1990). Under Pennsylvania law, therefore, a plaintiff may state a claim for punitive damages by alleging that the defendant had actual knowledge of the risk imposed to the health and welfare of another, and, in the face of that knowledge, acted, or failed to act, in conscious disregard of the risk.

Here, the Master Complaint properly alleges sufficient facts to support a finding by the jury that the P&G Defendants' conduct was so outrageous and evil so as to demonstrate a reckless indifference to others. *See e.g.*, Complaint ¶¶ 60, 61, 67-70. In particular, the Master Complaint alleges that the P&G Defendants knew through published scientific peer reviewed journal articles as early as 2007 that there is a link between denture fixatives with zinc, such as Fixodent, and zinc poisoning. *Id.* ¶¶ 67-69. It was also generally known and accepted that excessive zinc in the body would lead to adverse health effects in humans, including elevated zinc, copper deficiency and neurological disorders. *Id.* ¶¶ 60, 61. The Master Complaint also alleges that the P&G Defendants had knowledge because in 2006 lawsuits were filed against GSK, P&G's largest competitor, alleging that denture adhesives caused zinc poisoning. *Id.* ¶¶ 53, 64.

Indeed, the Master Complaint cites the Hedera article, which reports on a study of eleven patients, at least four of whom used Fixodent. *See* Exhibit B at 1. The Hedera Abstract summarizes:

> We analyzed the origin of excessive zinc in eleven patients with a progressive myelopolyneuropathy and unexplained hypocupremia with hyperzincemia. These patients had a detailed clinical assessment, determination of zinc and copper levels, and analyzed use denture cream [including Fixodent] with the estimates of zinc exposure. ***We identified denture cream [including Fixodent] as a source of excessive zinc in 100% patients in our cohort.*** They all had a history of ill-fitting dentures requiring large amounts of denture cream, resulting in significant zinc exposure. Their copper and zinc normalized after stopping denture cream, further confirming that this is the source of high zinc. Inappropriate use of denture cream appears to be the sole source of excessive zinc in these patients. *Id.* at 1 (emphasis added); *see* Complaint ¶68.

Despite this clear and undeniable knowledge, P&G has egregiously failed to warn consumers

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about the potential permanent and profound personal injuries and enduring disabilities its Fixodent products can cause or even, at a minimum, warn that Fixodent contains zinc. *Id.* ¶¶ 16, 43. For months and sometimes years, Plaintiffs have gone undiagnosed or have been unable to find the source of their excessive zinc exposure (which appeared in blood serum and urine tests), while the P&G Defendants knowingly have stood silent about the zinc in its products. *Id.* ¶¶ 69-70.

In *McDaniel v. Merck*, 533 A.2d 436 (Pa. Super. 1987), the Superior Court recognized that the Plaintiff had provided sufficient facts for a punitive damages claim against a drug manufacturer. The *McDaniel* plaintiff alleged that Merck "knew of a serious risk of illness and death" resulting from use of the drug and that it "failed to communicate" that information. *Id.* at 447- 48. The *McDaniel* Court ruled that the Merck's failure to act, in the face of a serious risk of injury to consumers, was sufficient to allow the claim for punitive damages.

Here, the facts are even more outrageous than in McDaniel. Fixodent is an over-the-counter product any consumer can buy, P&G does not provide any information to consumers that it contains zinc, and no warning that use of Fixodent can result in zinc poisoning, copper deficiency and neurological injury. By P&G remaining silent on the zinc issue to this day, despite the medical evidence available, is plainly recklessly indifferent to the life and health of Fixodent users. The P&G Defendants should not be permitted to hide behind marking their internal documents confidential, thus preventing their use in conjunction with these Preliminary Objections, and their false claims of ignorance to achieve an early dismissal of punitive damages in these cases. The record, even at this early stage of the litigation, is more than sufficient to overcome the P&G Defendants' Preliminary Objections.

Therefore, Plaintiffs' respectfully request that Defendants' Preliminary Objections be denied.

V. CONCLUSION

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Wherefore, and for the reasons set forth herein, Plaintiffs' respectfully request that this Honorable Court deny Defendants' Preliminary Objections.

Dated: January 6, 2010

Respectfully submitted,

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VERIFICATION

I, ERIC T. CHAFFIN, ESQUIRE, hereby state that I am attorney for plaintiffs and that the facts set forth in the foregoing Responses to the Preliminary Objections are true and correct to the best of my knowledge, information and/or belief. I understand that false statements made herein are subject to the penalties of 18 Pa. C.S.A. §4904 relating to unsworn falsification to authorities.

BY: _____
ERIC T. CHAFFIN

Dated: 1/6/10

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CERTIFICATE OF SERVICE

I, Lee B. Balefsky, Esquire, hereby certify that a true and correct copy of Plaintiffs' Responses to the Defendants' the Procter & Gamble Manufacturing Company and the Procter & Gamble LLC Preliminary Objections to Plaintiffs' Master Long Form Complaint was served upon all counsel of record via ECF Filing and/or email on January 6, 2010.

LEE B. BALEFSKY, ESQUIRE

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Exhibit A

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Via Email

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Re: In Re: Denture Cream Products Liability Litigation
United States District Court, Southern District of Florida
Case No. 09-2051-MD-ALTONAGA/Brown

In Re: Denture Adhesive Cream Litigation, June Term 2009, No. 4534
In the Court of Common Pleas, Philadelphia County, Pennsylvania

Dear Melissa:

Plaintiffs write to follow-up on our meet-and-confer this afternoon regarding P&G's production deficiencies in the above-captioned litigations. Please allow this letter to confirm our conversation and to address various issues that need follow-up.

First, P&G represented that its productions to date contain documents from a "central records" collection, hard copy documents from various storage areas at P&G, adverse events files, consumer complaints and a small number of electronic documents (which is no more than some marketing data that was on an electronic CD).

Second, P&G represented that there was an error in the meta-data produced in the P&G productions to date and that you first identified the problem based upon Plaintiffs' letter of October 21, 2009. P&G represented that this error is being corrected and replacement productions are being produced this Friday, October 30, 2009.

Third, P&G represented that to date it has produced approximately 17,000 to 20,000 pages of consumer complaints in .pdf format because of an unidentified problem

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with converting the data to .tiff images with single page load files. You represented that these pages were converted to .pdf from their original format, which was an electronic database. Plaintiffs request that P&G identify the database and produce the discoverable data in native electronic format (after discussions with Plaintiffs about the format of the data, including whether it can be produced in a Microsoft Access, ASCII comma delimited format, or another format) that would allow it to be more readily accessed and reviewed by Plaintiffs.

Fourth, Plaintiffs asked whether the consumer complaints included any audio recordings and you represented that P&G does not have any such recordings (as you had previously requested such recordings from P&G and were not provided any). To the extent this is incorrect, we ask that you inform us immediately and Plaintiffs of course reserve the right to call for production of any such recordings.

Fifth, P&G represented that the adverse event ("AE") files produced to date are from "hard copy" documents that have only limited meta-data. P&G represented, however, that there is AE information available in electronic format (the "initial call-in" and "report to the FDA" information) even though you think this information is duplicative of AE information produced in hard-copy format. Plaintiffs ask that P&G produce the electronically available information and, based on discussions to date, do not believe that it is duplicative because the electronic documents will undoubtedly contain meta-data and other electronic information that is not available in the cumbersome hard-copy productions.

Sixth, to date P&G has produced less than one-third of the documents that it anticipates producing in this litigation (approximately 87,000 of 300,000 pages) and you informed Plaintiffs for the first time that you anticipate P&G completing this production in or about late December 2009. This concerns Plaintiffs on multiple levels, including that it will unduly delay the progress of this litigation, is inconsistent with what Plaintiffs have been led to believe about P&G's production, is inconsistent with what is expected under the Case Management Orders in the above-captioned courts, and Plaintiffs do not believe that they have adequate information to serve the Master Interrogatories on P&G called for in the Case Management Orders in the above-captioned litigations.

Seventh, Plaintiffs renew their request that P&G produce a production log similar to that which GSK has done, which should include at the very least, the name of the custodian or source of the documents, the last job title or department of the custodian, a description of the documents produced for the custodian (emails, hard copy documents, etc.), the bates numbers (ranges) of the documents produced for the custodian, the date produced and the rolling production number. While you represented that you did not previously agree to produce such a log, we believe that such a log was agreed to when P&G represented in August that it would follow GSK's production format in this litigation. If P&G wanted to make exception to the process, it should have done so in August. Accordingly, Plaintiffs request that P&G produce a log of its current productions and update it on a simultaneous basis with ongoing future productions.

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Eighth, you represented that P&G will make its next (new) production on Monday, November 2, 2009. You stated that the production will include consumer comment, marketing and patent documents. You further represented that with the exception of a single individual custodian, Ms. Hein, P&G has not made any productions of electronically stored documents so far. You stated that on Monday, November 2, P&G will produce the first individual custodian documents and you thought that the production would include electronic and hard copy documents for approximately five custodians (even though as Plaintiffs understand it, P&G has interviewed approximately 65 P&G employees as part of its investigation into the issues in this case).

Ninth, P&G represented that most of its production to date is from the "central storage index" which you described as a list of documents in central storage at P&G that you searched to identify potentially discoverable materials. You stated that you have personally seen only two fields from this index, the document name and date the document was received at the central storage location. Plaintiffs ask that you identify the additional fields that are available in the index, including for example whether the index identifies the name of the person who sent the documents to central storage. Plaintiffs further request that you produce the available fields in the index for the documents produced in this litigation.

Tenth, you stated that you used search terms to gather and produce documents in this litigation and Plaintiffs request that you produce those search terms.

Eleventh, you represented that a number of the productions to date came from unidentified "storage closets" at P&G. Plaintiffs asked that these locations be identified. Further, Plaintiffs inquired whether P&G produced custodial information for these documents in the production, including for example, the covers of any folders for the produced documents. You represented that you were unsure and noted that there was at least one storage closet where the contents of binders were produced but that you needed to confirm whether the covers of those binders were in fact produced to Plaintiffs. We ask that you confirm that the hard copy documents are being produced as they are kept in the ordinary course of business, including with cover pages, face sheets and folder covers as available.

Twelfth, P&G represented (again) that it will produce the electronic documents in these litigations in the same formats as earlier agreed to and Plaintiffs again reserve the right to request documents in native format (which is particularly important to Plaintiffs in light of the production issues to date).

Thirteenth, Plaintiffs renewed their prior request that P&G determine whether potentially discoverable materials have been preserved in other litigations. This issue arose previously during discussions in the Pennsylvania litigation about P&G's preservation of documents and electronic information and specifically P&G's email retention policies. Your response today was that P&G is unwilling to do this. Plaintiffs ask that P&G confirm whether any of the custodians who were interviewed as potentially having discoverable materials in this litigation were previously the subject of any

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litigation hold notice prior to the one done in these litigations and, if so, the dates of those notices and whether any documents or information preserved for the unrelated litigations exist today.

Fourteenth, we have asked P&G to identify employees who have received litigation hold notices in these cases, which GSK has already done for its employees.

Fifteenth, P&G represented that it does not retain all changes to company websites and it is not standard procedure to preserve all prior versions. Plaintiffs believe that this information is potentially discoverable and relevant, particularly regarding any representations made by P&G regarding the safety, effectiveness or risks associated with any Fixodent products containing zinc. Accordingly, Plaintiffs renew their request that P&G preserve any and all changes to areas of websites at least on these issues while this litigation is pending. To the extent this is not done and confirmed, Plaintiffs reserve the right to bring an appropriate motion before the Courts, including a spoliation of evidence motion.

Finally, we asked that productions be made on DVDs rather than CDs and you agreed to do so.

Very truly yours,

Eric T. Chaffin, Esq.

cc: Frank Woodside, Esq. (by email)
Andy Alonso, Esq. (by email)
Scott Wm. Weinstein, Esq. (by email)
Roopal Luhana, Esq. (by email)

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Exhibit B

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NeuroToxicology xxx (2009) xxx–xxx

Contents lists available at ScienceDirect

NeuroToxicology

Research paper

Myelopolyneuropathy and pancytopenia due to copper deficiency and high zinc levels of unknown origin II. The denture cream is a primary source of excessive zinc

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ABSTRACT

Neurodegeneration of the central and peripheral nervous system associated with hypocupremia and hyperzincinemia has been widely recognized but the origin of high zinc remained unknown. Denture cream has been recently suggested as one possible source of zinc, but the frequency with which denture fixative alone accounts for this syndrome is unknown. We analyzed the origin of excessive zinc in eleven patients with a progressive myelopolyneuropathy and unexplained hypocupremia with hyperzincinemia. These patients had a detailed clinical assessment, determination of zinc and copper levels, and analyzed use of denture cream with the estimates of daily zinc exposure. We identified denture cream as a source of excessive zinc in 100% patients in our cohort. They all had a history of ill-fitting dentures requiring large amounts of denture cream, resulting in significant zinc exposure. Their copper and zinc normalized after stopping denture cream, further confirming that this is the source of high zinc. Inappropriate use of denture cream appears to be the sole source of excessive zinc in these patients.
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Since the initial description of hyperzincinemia associated with hypocupremia by our group (Hedera et al., 2003) and others (Prodan et al., 2002; Kumar et al., 2004a), the syndrome of myelopolyneuropathy with hematologic abnormalities has become widely recognized and reported (Greenberg and Briemberg, 2004; Kumar et al., 2004b; Schleper and Stuerenburg, 2001). Copper insufficiency is considered the main pathogenic mechanism of the neurological damage (Kumar, 2006). Hypocupremia may be secondary to reduced absorption caused by malabsorption, gastric resection or bariatric surgery (Kumar et al., 2003a; Spinazzi et al., 2007; Tan et al., 2006). Serum zinc levels in these circumstances are normal or only slightly elevated. Hypocupremia also occurs as the consequence of excessive oral zinc consumption (Brewer et al., 1977; Prasad et al., 1978; Hoffman et al., 1988; Broun et al., 1990; Gyorffy and Chan, 1992). In this circumstance, a high concentration of zinc in the small intestine induces enterocytic expression of metallothioneins, which bind copper (Yuzbasiyan-Gurkan et al., 1992). Copper remains in the enterocytes, is lost through intestinal epithelial turnover into the stool, and is not effectively absorbed into portal venous blood (Yuzbasiyan-Gurkan et al., 1992).

Although a few patients with identified external source of zinc have been reported, the source of hyperzincinemia has been an enigma for the majority of hyperzincemia/hypocupremia patients (Hedera et al., 2003; Hoffman et al., 1988; Broun et al., 1990; Gyorffy and Chan, 1992; Kumar et al., 2003b). Denture fixatives as a possible source of hyperzincemia was first reported by Spinazzi et al. (Spinazzi et al., 2007) and later emphasized in the report by Nations et al. (Nations et al., 2008). However, the frequency with which denture fixative alone accounts for instances of hyperzincemia previously considered idiopathic is unknown. This prompted us to reevaluate the use of denture fixative in 11 patients in which myelopolyneuropathy was associated with hypocupremia and hyperzincemia. Here we report that all of these patients had a history of poorly fitting dentures requiring the application of very high amounts of denture creams. For each patient, cessation of dental fixative use resulted in dramatic lowering of serum zinc concentration and elevation of serum copper concentration.

1. Methods

Plasma and urine copper and zinc levels were obtained through the clinical laboratories used for the clinical care. We estimated the

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amount of daily zinc exposure by asking the patient the approximate amount of cream needed per day for a typical application and the most commonly used brand of denture cream. We used the zinc concentration values reported by Nations et al. (Nations et al., 2008). If patients used both major brands (Poli-Grip and Fixodent), we used the brand with lower zinc concentration (Fixodent) for conservative estimates of daily zinc exposures. We then multiplied the reported intake (in estimated grams) times the zinc concentration to determine the daily zinc intake. Patients were also screened for other possible causes, including plasma vitamin B12 and vitamin E levels, plasma protein electrophoresis, and serologic testing for Lyme disease, HTLV1 and HIV.

2. Results

We identified eleven patients with previously unexplained hyperzincinemia and copper deficiency. Demographic and clinical data is summarized in the Table 1; subject #9 was previously reported (Hedera et al., 2003). Clinical features were quite uniform. Every patient reported numbness and paresthesia affecting the lower extremities as the initial symptom with a rapid progression to the upper extremities, and loss of balance. Neurologic examination showed deficits involving motor-sensory polyneuropathy and myelopathy (corticospinal tract and dorsal columns). Bone marrow suppression was evident in all subjects (pancytopenia in 9 subjects; isolated normocytic anemia in 2 subjects). Neuroimaging studies encompassing the whole neuroaxis were unremarkable with the exception of two patients. Patient #1 had abnormal signal on T2-weighted images confined to the region of dorsal columns in the cervical segments C1 through C5 with normal brain MRI; and patient #5 who had signs of centrum semiovale demyelinization; his cerebrospinal fluid analysis did not show any signs of inflammation or intrathecal production of immunoglobulins. Copper oral supplementation with a typical dose of 6 mg of copper/day (range 2–8 mg/day) resulted in improved copper levels in compliant patients. Only patient #4 required subcutaneous supplementation with 2 mg copper/day. All hematologic abnormalities resolved after copper supplementation, even though hyperzincinemia persisted. The degree of neurological improvement varied and is summarized in the Table 1.

We did not identify any obvious source of zinc at the time of initial diagnosis and previously known causes of hyperzincinemia, such as coin swallowing or an excessive intake of zinc supplements were ruled out. These individuals also did not have any relevant history of malabsorption or gastric surgeries with the exception of patient #8 who had a partial gastrectomy as a teenager. However, his copper and zinc abnormalities followed the same pattern as seen in other patients, arguing against a significant role of his gastric surgery. The same individual had also a 5-year history of taking zinc supplements containing approximately 230% of the US recommended daily allowances dose of zinc; this supplement also contained 1 mg of copper.

After the report of high zinc content in commonly used denture creams (Nations et al., 2008), we contacted all individuals and every patient reported a long-term use of dentures. Each subject described their dentures as poorly fitting and reported applying large amounts of the denture creams and often reported using dentures overnight. Estimated daily exposures and duration of the denture use are summarized in the Table 1. The patients were instructed to stop using denture cream and their copper and zinc values normalized. The shortest interval before the repeated laboratory evaluation was three weeks.

Additionally, marked reduction in hyperzincemia was associated with patient-initiated reduction in the use of denture fixative. Patient #7 had ~5-year history of progressive sensory ataxia, lower extremity hyperreflexia, and painful dysesthesia and persistent hyperzincemia, hypocupremia, and low serum ceruloplasmin. In the fall of 2008 she received a new pair of dentures which fit better and required much less use of denture adhesive. Urine zinc excretion prior to use of these new dentures (August 2008) measured 5032 μg/24 h and was markedly reduced (1295 μg/24 h, November 2008) after wearing new dentures and using less denture adhesive. Serum copper did not substantially change during this interval.

3. Discussion

Blocked copper absorption in the presence of increased zinc intake is a well-known phenomenon, resulting in the development of a negative copper balance (Brewer et al., 1977; Prasad et al., 1978; Hoffman et al., 1988; Broun et al., 1990; Gyorffy and Chan, 1992). This is, for example, the principle of the FDA approved use of zinc for maintenance therapy of Wilson's disease (Brewer et al., 1998; Brewer et al., 1999; Brewer, 2005). Long-term oral zinc therapy slowly removes accumulated copper and prevents the reaccumulation of copper, thereby protecting against further liver and brain damage (Brewer et al., 1998, 1999; Brewer, 2005; Brewer et al., 1987, 1989). However, an excessive zinc intake in non-Wilson's disease patients also leads to copper deficiency, manifesting as a combined degeneration of the spinal cord, polyneuropathy and bone marrow suppression (Hedera et al., 2003; Prodan et al., 2002; Kumar et al., 2004a; Greenberg and Briemberg, 2004; Kumar et al., 2004b; Schleper and Stuerenburg, 2001; Kumar, 2006; Kumar et al., 2003b). The obscure source of excessive zinc in several reported patients with a copper deficiency (human swayback disease) has been a problem for the medical community, because these patients typically suffer from a devastating neurological condition with a severe functional deficit. Furthermore, many patients only partially improved neurologically on copper supplementation in spite of relatively early recognition of the problem.

Detection of high zinc content in common brands of denture creams identified a possible source of excessive zinc intake (Nations et al., 2008). However, the frequency of the use of denture cream as the basis for a copper deficiency associated with severe neurologic and hematologic abnormalities was unknown. The main finding of this follow up report is the finding that 100% (eleven of eleven) patients followed by us with the copper deficiency syndrome ingested large amounts of zinc from denture cream, suggesting that probably most patients, if not all, with otherwise idiopathic hyperzincinemia have developed this problem due to application of high amounts of denture cream. These patients previously fit the concept of an idiopathic syndrome because their hypocupremia was not explained by any gastrointestinal absorption abnormalities and the hyperzincinemia was not solely explained by an inappropriate use of zinc supplements. One of the patients (subject #8) with a 17-year history of dentures had a partial gastrectomy and for a few years also took higher than recommended zinc supplementation; however, his copper and zinc abnormalities followed the same pattern as seen in other patients using denture cream. We did not identify any other possible contributing factors to hyperzincinemia, arguing against the causative role of his gastric surgery.

One of the unresolved issues is whether these patients are more susceptible than the general population of denture users to the exposure of increased zinc content, either by increased absorption or reduced elimination of zinc (Hedera and Brewer, 2004; Spinazzi and Armani, 2009). Additional shared characteristics in every reported individual included poorly fitting dentures requiring a prolonged application of large amounts of adhesive paste, with the average use of more than two tubes per week, containing approximately 80 g of the denture cream. The shortest duration of denture use was seven years with presumed similar daily use of the denture cream. We could only estimate daily zinc exposure and

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Table 1
Clinical and laboratory characteristics of studied patients.

Subject #: gender Age	#1: Male 48 years	#2: Male 51 years	#3: Male 54 years	#4: Female 39 years	#5: Male 48 years	#6: Female 42 years	#7:Female 51 years	#8: Male 69 years	#9: Male[a] 51 years	#10 Male 33 years	#11 Male 51 years
Age of symptom onset	45 years	49 years	53 years	38 years	41 years	40 years	45 years	66 years	46 years	31 years	44
Myelopathy: pyramidal tract (PS) signs	PS+	PS+	PS−	PS−	PS+	PS+	PS+	PS−	PS+	PS+	PS
Dorsal columns (DC) signs	DC+	DC+	DC+	DC+	DC+	DC+	DC+	DC+	DC+	DC+	DC+
Distal weakness	2/5	3/5	2/5	4/5	2/5	3/5	4/5	4/5	2/5	3/5	3/5
Gait	Wheelchair	Cane	Walker	Independent	Walker	Wheelchair	Wheelchair	Walker	Walker	Cane	Wheelchair
Polyneuropathy	+	+	+	+	+	+	+	+	+	+	+
Axonal (A), Demyelinization (D)	A, D	A	A	A, D	A,D	A,D	(EMG not performed)	A	A,D	A	A, D
Hematologic manifestation	Pan-cytopenia	Pan-cytopenia	Anemia	Pan-cytopenia	Anemia	Pan-cytopenia	Anemia	Pan-cytopernia	Pan-cytopenia	Pan-cytopenia	Pan-cytopenia
Initial copper and zinc plasma levels (ug/dL)[b]	Cu: 11 Zn: 145	Cu: 25 Zn: 121	Cu: 5 Zn: 132	Cu: 15 Zn: 160	Cu: 9 Zn: 154	Cu: 2 Zn: 171	Cu: 29 Zn: N/A	Cu: <20 Zn: N/A	Cu: 10 Zn: 184	Cu: <10 Zn: 175	Cu: 5 Zn:198
Initial copper and zinc urine levels (μg/24 h)[c]	Cu: 8 Zn: 1,390	Cu: undetectable Zn: 1,455	Cu: 10 Zn: 1,250	Cu: undetectable Zn: N/A	Cu: undetectable Zn: 2,294	Cu: undetectable Zn: N/A	Cu: 32 Zn: 5,010	Cu:9 Zn:2,661	Cu: 4 Zn: 5,010	Cu: N/A Zn: N/A	Cu: 3 Zn: 2,120
Highest cupper levels on supplementation (ug/dL)	Cu: 57 Zn: persistent hyper-zincinemia	Cu: 42 Zn: persistent hyper-zincinemia	Cu: 41 Zn: persistent hyper-zincinemia	Cu: 112 Zn: persistent hyper-zincinemia	Cu: 84 Zn: persistent hyper-zincinemia	Cu: 2[d] Zn: persistent hyper zincinemia	Cu: 138 Zn: persistent hyperzinemia	Cu: 75 Zn: persistent hyperzinemia	Cu: 67 Zn: persistent hyper zincinemia	Cu: 33 Zn: persistent hyper zincinemia	Cu: 75 Zn: persistent hyper zincinemia
History of dentures	10 years	20 years	15 years	7 years	11 years	10 years	11 years	17 years	18 years	15 years	25 years
Estimated daily zinc exposure (mg/24 H)	650–1,360	500–935	350–1,700	700–1,000	600–1,360	600–700	700–1,000	1,000–1,700	400–1,200	600–1,200	700–1,200
Preferred brand	Poli-Grip	Fixodent	Poli-Grip, Fixodent	Poli-Grip	Poli-Grip	Poli-Grip	Poli-Grip	Poli-Grip	Poli-Grip, Fixodent	Poli-Grip	Poli-Grip, Fixodent
Copper and zinc plasma levels after cessation of denture cream use ug/dL	Cu: 97 Zn: 106	Cu: 67 Zn: 98	Cu: 85 Zn: 112	Cu: 95 Zn: 114	Cu: 117 Zn: 119	Cu: 95 Zn: 118	Cu: 111 Zn: 78	Cu: 75 Zn:126	Cu: 102 Zn: 113	Cu: 88 Zn: 98	Cu:103 Zn: 87
Copper and zinc urine levels after cessation of denture cream μg/24 h	N/A	N/A	Cu: 27 Zn: 1,210	N/A	Cu: 9 Zn: 777	Cu: 11 Zn: 757	Cu: 16 Zn: 450	Cu: 15 Zn: 841	Cu: 8 Zn:1,864	Cu:12 Zn: 750	Cu: 22 Zn:980
Neurologic outcome	Remained wheelchair dependent	Improved balance, independent walking	No change, walking with support (walker)	Improved, almost complete recovery	Mild improvement, still walker dependent	No change, wheelchair dependent	Reduced pain	No change in his gait, Markedly improved sensory deficit	No significant change, walker dependent	Mild improvement, uses cane, feels more stable	Improved, can walk with walker

[a] Previously reported.
[b] Normal plasma levels (μg/dL): Cu 75–125; Zn 75–110.
[c] Normal urine levels (μg/24 h): Cu 20–50; Zn 200–500.
[d] Patient was not compliant with copper supplementation therapy.

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it varied from 350–1700 mg/day, even though the bioavailability of zinc from denture cream is unknown.

Relevant to this question is the experience with the therapy in Wilson's disease. In Wilson's disease, 75 mg of zinc per day in two or three divided doses, if taken separate from food, consistently produced negative copper balance (Brewer et al., 1993). In the eleven patients reported here, zinc intake was 5–23 times that amount. Presumably, most of the ingested cream was between meals, which makes the zinc much more effective in blocking copper absorption. Because of the enormous zinc quantities ingested by these patients, at this time we do not have to postulate an increased susceptibility to zinc.

In summary, poorly fitting dentures requiring large amounts of denture cream to provide a sufficient seal appear to be the common characteristics of patients with idiopathic hypocupremia, hyperzincinemia, bone marrow supression and a combination of polyneuropathy with spinal cord degeneration. Patients presenting with this constellation of neurologic and hematological signs need to be immediately screened for abnormal blood copper and zinc levels, and the use of large amounts of denture cream. It appears their disease is fully explained by denture cream use.

Conflict of interest

The authors declare that there are no conflicts of interest.

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Case ID: 090604534
Control No.: 09112680

Exhibit C

Case ID: 090604534
Control No.: 09112680

Important Product Information:

- This product contains zinc. Talk to your doctor before using this product if you are taking daily zinc supplements.
- Do not use if you have sensitivity to any of the cream ingredients. If discomfort occurs discontinue use.
- Swallowing small amounts of this product, when used as directed, may occur and is not harmful.
- Use only as directed in this insert. Using excessive amounts of this product over a prolonged period of time has been reported to result in serious health effects from increased zinc intake.

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Case ID: 090604534
Control No.: 09112680

For Best Results Start with a Small Amount

DIRECTIONS:
Super Poligrip holds all day. Apply once a day for secure hold. Start with a small amount. Using too much adhesive can cause oozing. If oozing occurs, use less adhesive next time. Do not apply more than once a day. A tube should last several weeks depending on size *(e.g., 0.75oz about 3 weeks, 1.4oz about 4 to 6 weeks, 2.4oz about 8 to 10 weeks)*. If not, you are using too much adhesive, which may be a sign of ill-fitting dentures.

See your dentist regularly. Routine dental examinations are part of good oral health and necessary to check the fit of your denture.

For the First Time, Start with a Small Amount

Use More If Needed

Upper Lower Partial

Recommended Size of Adhesive Strip Super Poligrip*

Actual size

LTUS4119A 60514XA

Case ID: 090604534
Control No.: 09112680