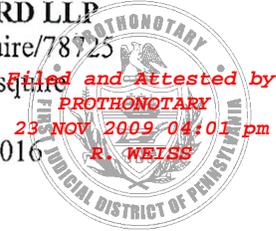


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Counsel for Plaintiff(s)

**IN RE: DENTURE ADHESIVE CREAM
LITIGATION**

**PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION**

June Term, 2009

No. 4534

**THIS DOCUMENT RELATES
TO ALL CASES**

PLAINTIFF(S)' MASTER LONG-FORM COMPLAINT AND JURY DEMAND

1. Pursuant to the July 20, 2009 Order by the Honorable Sandra A. Moss (the "Order"), the undersigned attorneys for Plaintiff(s) in the Denture Adhesive Cream Mass Tort Litigation Program bring this Master Complaint based upon counsel's investigation and upon information and belief.

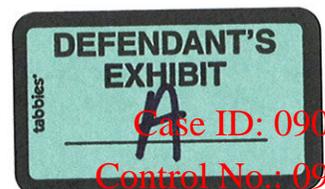
DEFENDANTS

2. This Master Complaint is against the following defendants:

**SMITHKLINE BEECHAM CORPORATION d/b/a
GLAXOSMITHKLINE**
One Franklin Plaza, 200 North 16th Street
Philadelphia, Pennsylvania 19102;

**GLAXOSMITHKLINE CONSUMER HEALTHCARE
L.L.C.**
1000 GSK Drive
Moon Township, PA 15108;

**GLAXOSMITHKLINE CONSUMER HEALTHCARE
L.P.**



1000 GSK Drive
Moon Township, PA 15108;

BLOCK DRUG COMPANY INC.
257 Cornelison Ave., Jersey City, New Jersey, 07302
C/O Corporation Service Company
830 Bear Tavern Road, West Trenton, NJ 08628

**THE PROCTER AND GAMBLE DISTRIBUTING
LLC**
One Procter & Gamble Plaza
Cincinnati, Ohio 45202,

**THE PROCTER & GAMBLE MANUFACTURING
COMPANY**
One Procter & Gamble Plaza
Cincinnati, Ohio 45202
C/O CT Corporation located at 1300 East 9th Street,
Cleveland, OH 44114

3. SMITHKLINE BEECHAM CORPORATION d/b/a

GLAXOSMITHKLINE, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C. and
BLOCK DRUG COMPANY INC. are hereinafter referred to collectively as (the “GSK
Defendants”).

4. THE PROCTER AND GAMBLE DISTRIBUTING LLC and THE
PROCTER & GAMBLE MANUFACTURING COMPANY are hereinafter referred to
collectively as the (“P&G Defendants”).

5. The GSK Defendants and the P&G Defendants are hereinafter collectively
referred to as the “Defendants(s).”

PLAINTIFF(S)

6. Pursuant to the Order, this Master Complaint is filed for all Plaintiff(s) or if
applicable, Plaintiff's spouse, child, decedent or ward represented by any Plaintiff(s)' counsel
who has signed agreement to the Master Complaint and, by operation of such order, all
allegations pleaded herein are deemed pleaded in any “Short-Form Complaint” hereafter filed,

unless otherwise indicated in a particular Short-Form Complaint.

DEFENDANT(S)' DENTURE CREAMS WITH ZINC

7. The over-the-counter (“OTC”) denture creams that are alleged to have injured and harmed Plaintiff(s) in this litigation include all denture creams with zinc that were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by the P&G Defendants, include (and hereinafter are collectively referred to as “FIXODENT”), but are not limited to, the following:

- a. FIXODENT ORIGINAL;
- b. FIXODENT FREE;
- c. FIXODENT CONTROL;
- d. FIXODENT CONTROL PLUS SCOPE FLAVOR;
- e. FIXODENT CONTROL TO GO;
- f. FIXODENT COMPLETE;
- g. FIXODENT FRESH;
- h. FIXODENT COMFORT;
- i. FIXODENT EXTRA HOLD POWER; and
- j. FIXODENT REGULAR HOLD POWDER.

8. The OTC denture creams that are alleged to have injured and harmed Plaintiff(s) in this litigation include all denture creams with zinc that were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by the GSK Defendants, include (and hereinafter are collectively referred to as “SUPER POLIGRIP”), but are not limited to, the following:

- a. SUPER POLIGRIP ORIGINAL;
- b. SUPER POLIGRIP FREE (from in or about May 2003 through 2006);

- c. SUPER POLIGRIP ULTRA FRESH; and
- d. SUPER POLIGRIP EXTRA CARE WITH POLISEAL.

9. Collectively, FIXODENT and SUPER POLIGRIP are referred to hereinafter as "denture creams with zinc."

FACTUAL ALLEGATIONS

10. This is an action for damages suffered by Plaintiff(s) as a direct and proximate result of Defendant(s)' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of denture creams containing zinc.

11. Defendant(s) developed, designed, formulated, manufactured, packaged, labeled, advertised, marketed, instructed on and warned about, distributed and sold FIXODENT and SUPER POLIGRIP, since at least 1990 and 1996, respectively.

12. SUPER POLIGRIP and FIXODENT are FDA Class I medical devices.

13. SUPER POLIGRIP and FIXODENT contain a form of zinc which is bonded to a chemical of unknown formulation.

14. Plaintiff(s) aver that when SUPER POLIGRIP and FIXODENT are foreseeably swallowed and/or otherwise exposed to the user's gastrointestinal tract and as a result, zinc in excess amounts is absorbed in the body's tissues, upsetting mineral homeostasis and resulting in depleted copper levels in the body. This copper depletion results in the development of, *inter alia*, a constellation of neurological symptoms and injuries.

15. By the time these symptoms are noticed and eventually connected to excess zinc and copper depletion, permanent neurological and other physical injury has already been suffered by the user.

16. While cessation of SUPER POLIGRIP and FIXODENT generally results in

a return to normal zinc and copper levels, symptoms generally do not improve. The former user is thus left with permanent, profound personal injuries, and enduring disabilities.

GSK DEFENDANTS

17. Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE is a Pennsylvania Corporation, which has its principal place of business at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19102.

18. At all times material hereto, Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling SUPER POLIGRIP.

19. Defendant, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C. is a Pennsylvania Limited Liability Company which has its principal place of business at 1000 GSK Drive, Moon Township, PA 15108.

20. Upon information and belief, Defendant, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C., is a wholly owned subsidiary of Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE.

21. At all times material hereto, Defendant, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling SUPER POLIGRIP.

22. Defendant, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.P. is a Delaware Limited Partnership, which, upon information and belief, has Defendant, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C., acting as general partner.

23. At all times material hereto, Defendant, GLAXOSMITHKLINE

CONSUMER HEALTHCARE L.P. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling SUPER POLIGRIP.

24. The Defendant, BLOCK DRUG COMPANY INC. is a New Jersey corporation with a last known address of 257 Cornelison Ave., Jersey City, New Jersey, 07302. It may be served on its registered agent Corporation Service Company located at 830 Bear Tavern Road, West Trenton, NJ 08628.

25. Upon information and belief, the Defendant, BLOCK DRUG COMPANY INC. was acquired in 2001 by and is now a wholly owned subsidiary of the Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE.

26. At all times material hereto, Defendant, BLOCK DRUG COMPANY INC. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling SUPER POLIGRIP.

27. Upon information and belief, the Defendant, BLOCK DRUG COMPANY INC., was present and doing business in the United States generally and the Commonwealth of Pennsylvania and Philadelphia County in particular.

28. Defendant(s) SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C. and GLAXOSMITHKLINE CONSUMER HEALTHCARE, L.P. developed, designed, formulated, manufactured, tested, packaged, labeled, advertised, marketed, distributed and have sold SUPER POLIGRIP denture adhesive product.

29. Furthermore, despite Defendants SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C., and GLAXOSMITHKLINE CONSUMER HEALTHCARE, L.P., and/or BLOCK DRUG

COMPANY, INC.'s purported business associations and corporate structures, Plaintiff(s) allege that Defendants GLAXOSMITHKLINE CONSUMER HEALTHCARE L.P. and GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C. and/or BLOCK DRUG COMPANY, INC., are and were, at all relevant times, actually the "alter egos" of Defendant SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE such that the acts, omissions, and/or transgressions of Defendants GLAXOSMITHKLINE CONSUMER HEALTHCARE L.P., GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C. and/or BLOCK DRUG COMPANY, INC. were the acts, omissions, and/or transgressions of Defendant SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE because Defendant SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE exerted and continues to exert, and/or had and continues to have the right to exert, control, over all aspects of the development, design, formulation, manufacturing, testing, packaging, labeling, advertising, marketing, distributing and selling of SUPER POLIGRIP denture adhesive products while Defendants GLAXOSMITHKLINE CONSUMER HEALTHCARE L.P., GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C., and/or BLOCK DRUG COMPANY, INC. are and were, at all relevant times, shell entities that are undercapitalized, without a sufficient number of employees and/or staff of their own, without sufficient assets of their own, and/or without proper procedures required of such purported entities.

30. Plaintiff(s) further allege that Defendants SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE, GLAXOSMITHKLINE CONSUMER HEALTHCARE L.L.C., GLAXOSMITHKLINE CONSUMER HEALTHCARE, L.P. and/or BLOCK DRUG COMPANY, INC. are and were, at all relevant times, the agents, employees, and/or representatives of each other and were acting in furtherance and in the course and scope of said agency, employment, and/or representation in doing the acts, omissions, and transgressions

herein alleged.

P&G DEFENDANTS

31. THE PROCTER AND GAMBLE DISTRIBUTING LLC is an Ohio Corporation, which has its principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. It may be served on its registered agent CT Corporation located at 1300 East 9th Street, Cleveland, OH 44114.

32. At all times material hereto, THE PROCTER AND GAMBLE DISTRIBUTING LLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling FIXODENT.

33. Upon information and belief, at all relevant times, THE PROCTER AND GAMBLE DISTRIBUTING LLC was present and doing business in the Commonwealth of Pennsylvania and Philadelphia County in particular.

34. At all relevant times, THE PROCTER AND GAMBLE DISTRIBUTING LLC transacted, solicited, and conducted business in the Commonwealth of Pennsylvania and derived substantial revenue from such business.

35. At all relevant times, THE PROCTER AND GAMBLE DISTRIBUTING LLC expected or should have expected that its acts would have consequences within the Commonwealth of Pennsylvania.

36. THE PROCTER & GAMBLE MANUFACTURING COMPANY is an Ohio Corporation, which has its principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. It may be served on its registered agent CT Corporation located at 1300 East 9th Street, Cleveland, OH 44114.

37. At all times material hereto, THE PROCTER & GAMBLE MANUFACTURING COMPANY was engaged in the business of designing, developing,

manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling
FIXODENT.

38. Upon information and belief, at all relevant times, THE PROCTER & GAMBLE MANUFACTURING COMPANY was present and doing business in the Commonwealth of Pennsylvania and the County of Philadelphia in particular.

39. At all relevant times, THE PROCTER & GAMBLE MANUFACTURING COMPANY transacted, solicited, and conducted business in the Commonwealth of Pennsylvania and derived substantial revenue from such business.

40. At all relevant times, THE PROCTER & GAMBLE MANUFACTURING COMPANY expected or should have expected that its acts would have consequences within the Commonwealth of Pennsylvania.

41. THE PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE DISTRIBUTING LLC developed, designed, formulated, manufactured, tested, packaged, labeled, advertised, marketed, distributed and have sold FIXODENT denture adhesive product.

42. Plaintiff(s) are further informed and believe and thereon allege that Defendants THE PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE DISTRIBUTING LLC are and were, at all relevant times, the agents, employees, and/or representatives of each other and were acting in furtherance and in the course and scope of said agency, employment, and/or representation in doing the acts, omissions, and transgressions herein alleged.

FIXODENT

43. FIXODENT is a formulation of a zinc based dual-salt with a calcium-zinc bond of an unknown origin. It is marketed and sold in the United States in a tube that comes in a

box. FIXODENT typically comes in 2.4, 2.2, 1.4 and 1.2 ounce tubes. Neither the FIXODENT tube nor the box contain: any information about Fixodent's ingredients; identify FIXODENT as containing zinc; identify the amount of zinc in a single dose of FIXODENT (*i.e.*, that 1 gram of FIXODENT contains 17 milligrams of zinc); a clear recommended dosage of FIXODENT per day; a clear maximum dosage of FIXODENT to be used per day; and a statement that using more than a certain limited dosage of FIXODENT can lead to zinc poisoning, copper deficiency, neurological injuries or any other type of adverse health event.

44. The P&G Defendants fail to provide any warnings that using FIXODENT in any amount can lead to zinc poisoning, copper deficiency and serious physical injuries.

SUPER POLIGRIP

45. SUPER POLIGRIP is a formulation of a zinc based dual-salt with a calcium-zinc bond of any unknown origin.

46. Like FIXODENT, SUPER POLIGRIP is marketed and sold in the United States in a tube that comes in a box. SUPER POLIGRIP typically comes in 2.4 ounces and 1.4 ounce sized tubes.

47. Unlike FIXODENT, since in or about 2007, GSK has listed SUPER POLIGRIP's ingredients on the box that SUPER POLIGRIP is sold in. GSK added the ingredients in 2007 after settling lawsuits by consumers allegedly poisoned from zinc in SUPER POLIGRIP. The SUPER POLIGRIP ingredients, however, appeared only on the box, not on the tube of SUPER POLIGRIP. The ingredients listed were not accompanied by any specific information about zinc, such as a statement that each use of SUPER POLIGRIP under a strict reading of the best instructions provided by the GSK Defendants contains an amount zinc that is itself at or above the upper most limit of zinc that a person should be exposed to on a daily basis.

48. Further, neither the SUPER POLIGRIP tube nor the box that accompanied it

contained: a clear recommended dosage of SUPER POLIGRIP per day; a clear maximum amount of SUPER POLIGRIP to be used per day or a specified period of time; and did not in any way state that using more than a certain limited dosage of SUPER POLIGRIP can lead to zinc poisoning, copper deficiency, neurological injuries or any other type of adverse health event.

49. The GSK Defendants historically only provide minimal directions for SUPER POLIGRIP use that, at best, are confusing and misleading because they suggest, for example, that a consumer can use more SUPER POLIGRIP than identified in the instructions if they consult with their dentists first. Dentists, however, would not know of the significant and serious risks posed to SUPER POLIGRIP consumers' and Plaintiff(s)' zinc-copper balance or the risk of resulting neurological disorder from using more SUPER POLIGRIP than the vague and poor instructions provide. Moreover, as the GSK Defendants knew or should have known, many denture wearers do not regularly visit dentists and in fact have poor fitting dentures. Indeed, dentists are typically focused on an entirely different issue than the serious zinc issue; they are focused on issues such as the health of gums and jaw. There was simply no means for a consumer to connect a recommendation to visit their dentist before using more SUPER POLIGRIP to the potential for seriously debilitating physical injuries that Plaintiff(s) have suffered from SUPER POLIGRIP.

50. SUPER POLIGRIP currently comes in both zinc and zinc-free formulas with SUPER POLIGRIP FREE being the GSK Defendants' zinc free alternative. SUPER POLIGRIP with zinc was first introduced in the United States in or about 1996, when defendant BLOCK DRUG COMPANY changed to a Gantrez based tri-salt with zinc to develop a compound that could compete with FIXODENT's zinc-based denture cream. When Block introduced the zinc product in the United States, the adverse events for SUPER POLIGRIP

skyrocketed. As discussed *infra*, by 1998, Block had received its first report of zinc poisoning from one of its zinc based denture creams, Ultra Corega cream.

51. While the GSK Defendants changed to zinc based formulations for SUPER POLIGRIP around 1996, they did not use a zinc based denture cream formulation for SUPER POLIGRIP FREE. Consumers who reported adverse experiences related to zinc were steered by the GSK Defendants to SUPER POLIGRIP FREE, which at the time did not contain zinc.

52. In or about mid May 2003, however, GSK introduced SUPER POLGRIP FREE with the zinc tri-salt in the United States. Similar to what happened in 1996 with SUPER POLIGRIP, the number of adverse experiences reported by consumers related to SUPER POLIGRIP FREE skyrocketed.

53. Subsequently, in or about 2006, after two lawsuits were brought against GSK relating to consumers who were poisoned from zinc in denture cream, GSK changed SUPER POLIGRIP FREE's formulation back to a zinc free formula.

54. Most recently, in or about late September or early October 2009, the GSK Defendants changed the packaging on SUPER POLIGRIP. For the first time, each tube of SUPER POLIGRIP with zinc comes with a product insert. On the outer long side of the SUPER POLIGRIP box, it now reads: "Read NEW INFORMATION Inside," referring to the product insert. On the end of the SUPER POLIGRIP box, it now reads: "IMPORTANT Read Directions First." The following statement appears on the insert:

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.

55. The statements on the insert, however, fail to, *inter alia*, adequately warn consumers in a number of important respects, including, for example, they fail to warn consumers of the particular types of “serious health effects from increased zinc intake” will occur from using what the GSK Defendants characterize as “excessive amounts” of SUPER POLIGRIP and the statements misleading state that swallowing “small amounts” of SUPER POLIGRIP is “not harmful.”

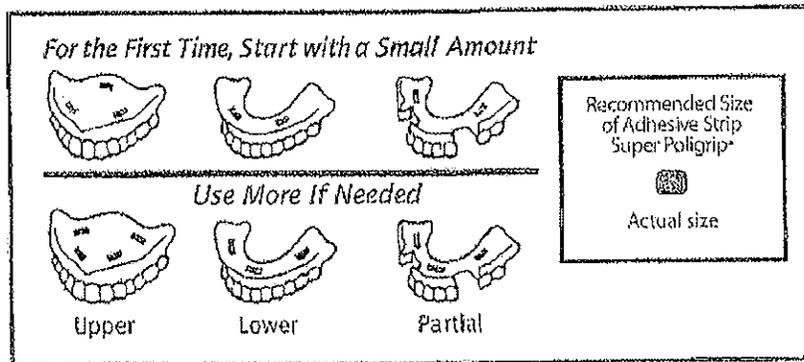
56. The GSK Defendants further revised SUPER POLIGRIP’s directions to include the following information for the first time in the history of SUPER POLIGRIP: a blanket statement to consumers not to use SUPER POLIGRIP more than once per day (rather than the generally false and misleading suggestion that SUPER POLIGRIP is safe for a consumer to use more than once per day if used in consultation with a dentist); a statement of the number of weeks that each sized tube of SUPER POLIGRIP should last if the tube is used as directed; and a measurement diagram to measure the “actual size” of a strip of SUPER POLIGRIP to be applied. SUPER POLIGRIP directions now provide:

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.



DEFENDANTS KNOWINGLY CONCEALED THE FIXODENT AND SUPER POLIGRIP ZINC PROBLEM

57. Defendant(s) knew that SUPER POLIGRIP and FIXODENT would be placed in the wet mouths of consumers who used the denture creams to secure their dentures.

58. Defendant(s) further knew or should have known that SUPER POLIGRIP and FIXODENT would be absorbed through the wet gums and that a larger amount of SUPER POLIGRIP and FIXODENT would be swallowed and result in exposure of the denture cream, including the zinc therein, to the gastro-intestinal tract and metabolized.

59. Defendant(s) further knew that: they did not provide clear and consistent

directions for use or dosage instructions to consumers; they left dosage information to a consumer's discretion and encouraged them to use more as needed to secure their dentures; that consumers who used denture cream to secure dentures were prone to use significant amounts of denture cream, resulting in the consumers swallowing more FIXODENT and SUPER POLIGRIP than Defendant(s) knew was safe for consumption; and exposure to the zinc in SUPER POLIGRIP and FIXODENT could lead to zinc poisoning, copper deficiency, neurological damage and other injuries.

60. Prior to and since 1990 when zinc was added to Fixodent and 1996 when zinc was added to SUPER POLIGRIP, it was generally known and accepted in the scientific community that excess zinc in the body could lead to adverse health effects in humans, including elevated zinc, copper deficiency and neurological disorders.

61. Given the state of scientific knowledge and understanding at the time zinc was added to SUPER POLIGRIP and FIXODENT and since then, Plaintiff(s) aver that it was impossible and implausible that Defendant(s) were then unaware of the likely adverse effects in humans associated with the chronic exposure to zinc attributable to Plaintiff(s)' use and ingestion of SUPER POLIGRIP and/or FIXODENT, including hyperzincemia, hypocupremia and neurological injuries. Defendant(s) were further made aware of the dangers of SUPER POLIGRIP and FIXODENT as a result of numerous complaints about SUPER POLIGRIP, FIXODENT and other zinc based denture creams.

62. Indeed, as early as 1998, Defendant BLOCK DRUG COMPANY received a report of an adverse event alleging that Ultra Corega Cream. Ultra Corega Cream is a zinc denture cream similar to SUPER POLIGRIP that, upon information and belief, was sold in Europe in 1998. The adverse event report alleged that the patient, who used the cream twice daily, was poisoned from zinc in the denture cream and developed neurological type injuries.

63. There also have been a number of adverse events reported by Defendant(s) (and others) to the U.S. Food & Drug Administration (“FDA”), including reports of neuropathy specifically. For example, in November 2005, two separate “medically serious” incidents of neuropathy allegedly caused by zinc toxicity from using Poligrip were reported to the FDA. Despite these and other adverse event reports, Defendant(s) did not take any action to warn consumers about the risk of zinc toxicity, copper deficiency or neurological damage from SUPER POLIGRIP.

64. In 2006 and again in 2007 lawsuits alleging personal injuries from excess zinc absorption were filed against the GSK Defendants.

65. As a result of the growing concern regarding the safety of SUPER POLIGRIP as evidenced by the two lawsuits, the GSK Defendants caused to be published and disseminated to the media and *via* the Internet, the following false and misleading statement regarding SUPER POLIGRIP:

GlaxoSmithKline Consumer Healthcare stands by the safety and efficacy of SUPER POLIGRIP, which is approved and regulated by the Food and Drug Administration (FDA). Although we can't comment on this person's claim, we want to assure consumers that Super Poligrip is safe and effective when used as directed. When someone uses Super Poligrip for their dentures, the vast majority of the zinc in the product remains in the adhesive and is not released into the mouth. Thus the potential for absorption of zinc through the gums is minimal. Although it is expected that a small amount of Super Poligrip would be swallowed when used as directed, the amount of zinc that is released into the stomach and absorbed into the bloodstream is very small. Therefore, the possibility of experiencing adverse effects from exposure to zinc in Super Poligrip is highly unlikely when the product is used as directed. Zinc is an essential mineral that is found in almost every cell in the body and in foods like red meat, poultry, whole grains and beans and is necessary for the maintenance of good health and nutrition. Zinc is a very common ingredient in many over-the-counter and FDA approved products.

66. This statement is likely to mislead and misleads consumers, including, but

not limited to Plaintiff(s) herein, in that, *inter alia*, it claims that SUPER POLIGRIP is safe and effective and purports to apportion blame for any adverse events on deviation from use as directed, although the GSK Defendants, and each of them, failed to provide any directions that might reasonably address preventing deviation from directed use and/or provide any warning that would warn consumers in any reasonable way that deviation from use would result in serious bodily injury.

67. In June 2008, an article published in the respected scholarly journal "Neurology" addressed the issue of zinc in SUPER POLIGRIP and FIXODENT. The article specifically linked excess zinc in FIXODENT and SUPER POLIGRIP, at levels of approximately 17 milligrams to 34.2 milligrams respectively to hyperzincemia and hypocupremia, which was determined to be the cause of "profound neurologic disease" in the patients reviewed. The abstract conclusion stated: "Denture cream contains zinc, and chronic excessive use may result in hypocupremia and serious neurologic disease."

68. More recently, in September 2009, an article published in the scholarly journal *NeuroToxicology* addressed the issue of zinc in denture creams such as SUPER POLIGRIP and FIXODENT. This research paper is 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*" (hereinafter "*NeuroToxicology Article*"). The authors of the *NeuroToxicology Article*, researchers in the field of zinc poisoning and copper deficiency, had studied 11 patients who had developed significant injuries, including zinc poisoning, copper deficiency and neurological disorders for a period of years. Each of the patients in the study suffered significant neurological and hematological injuries like the Plaintiff(s) and, for example, many of the patients were dependent on canes, walkers or wheelchairs because the neurological injuries were so profound. For a number of years, the

authors could not identify the origin of the high blood zinc levels in patients who had been studied and/or treated by the authors for many years. In 2009, the authors went back to each of the 11 patients and found that *all 11 patients* used SUPER POLIGRIP and/or FIXODENT and confirmed through blood tests that each of them suffered from zinc poisoning and copper deficiency, which normalized after the 11 patients ceased using SUPER POLIGRIP and/or FIXODENT. The authors concluded:

Denture fixatives as a possible source of hyperzincemia was first reported by Spinazzzi et al. (Spianzzi 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 application of very high amounts of denture creams. For each patient, cessation of dental fixatives used resulted in dramatic lowering of serum zinc concentration and elevation of serum copper concentration.*

* * * *

It appears their disease is fully explained by denture cream use.

(emphasis added).

69. Despite clear and undeniable knowledge of the link between chronic exposure to excess zinc and injury to humans, including profound, irreversible, neurological damage caused by hyperzincemia and hypocupremia, Defendant(s) have and continue to formulate, manufacture, distribute, market, label, and sell SUPER POLIGRIP and FIXODENT to consumers in the Commonwealth of Pennsylvania and throughout the United States, concealing this serious health hazard, and omitting from their packaging and labeling any or adequate warnings, instructions, directions or other information regarding, *inter alia*, health concerns, safe use, or even defining what Defendant(s) might believe to be “excessive” use of

the products. The Defendant(s) failures caused the initial injuries and the continuation of them because Plaintiff(s) suffered many months and years of poisoning and disabilities that went undiagnosed and untreated as a result of Defendant(s) concealment and failure to disclose the zinc problem with FIXODENT and SUPER POLIGRIP.

70. In omitting and concealing this critical safety information regarding use of SUPER POLIGRIP and FIXODENT to induce the purchase and use of SUPER POLIGRIP and FIXODENT, Defendant(s), and each of them, engaged in and continue to engage in conduct likely to mislead consumers including, but not limited to, Plaintiff(s) herein, and which is fraudulent, unfair, and unlawful.

71. Plaintiff(s) have suffered from zinc toxicity, copper deficiency, profound and permanent neurological damage and other injuries attributable to her SUPER POLIGRIP and FIXODENT use, which injuries have left Plaintiff(s) unable to perform their normal, customary and daily activities.

72. Plaintiff(s)' injuries and disabilities are a result of an actionable defect in the SUPER POLIGRIP and FIXODENT used by Plaintiff(s) and negligence on the part of Defendant(s).

73. Had Defendant(s) properly disclosed the risks associated with SUPER POLIGRIP and FIXODENT and/or provided adequate warnings, Plaintiff(s) would not have used these products and/or used a significantly less amount within the range of safe use.

74. As alleged herein, as a direct and proximate result of the Defendant(s)' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of SUPER POLIGRIP and FIXODENT, Plaintiff(s) suffered severe and permanent physical injuries, including but not limited to profound and permanent neurological injuries. Plaintiff(s) have endured substantial pain and suffering. Plaintiff(s) have incurred significant expenses for

medical care and treatment, and will continue to incur such expenses in the future. Plaintiff(s) have suffered a loss of earning capacity. Plaintiff(s) have suffered and will continue to suffer economic loss, and/or have otherwise been physically, emotionally and economically injured. Plaintiff(s)' injuries and damages are permanent and will continue into the future. The Plaintiff(s) seek actual and punitive damages from the Defendant(s) as alleged herein.

COUNT I
(NEGLIGENCE)

75. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

76. At all times material hereto, Defendant(s), and each of them individually, had a duty to exercise reasonable care to consumers, including Plaintiff(s) herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of SUPER POLIGRIP and FIXODENT.

77. Defendant(s), and each of them individually, breached their duty of reasonable care to Plaintiff(s) in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold SUPER POLIGRIP and FIXODENT.

78. Plaintiff(s)'s injuries and damages alleged herein were and are the direct and proximate result of the Defendant(s) carelessness and negligence:

- a. In their design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of SUPER POLIGRIP and FIXODENT;
- b. In their failure to warn or instruct, and/or adequately warn or adequately instruct, users of SUPER POLIGRIP and FIXODENT, including Plaintiff(s) herein, of SUPER POLIGRIP and FIXODENT dangerous and defective characteristics;

- c. In their failure to warn or instruct and/or adequately warn or adequately instruct, users of SUPER POLIGRIP and FIXODENT, including Plaintiff(s) herein, not to use zinc supplements while using SUPER POLIGRIP and FIXODENT;
- d. In their design, development, implementation, administration, supervision and/or monitoring of any clinical trials for SUPER POLIGRIP and FIXODENT;
- e. In their promotion of the subject product in an overly aggressive, deceitful and fraudulent manner, despite evidence as to SUPER POLIGRIP's and FIXODENT's defective and dangerous characteristics due to their propensity to cause serious injury;
- f. In representing that SUPER POLIGRIP and FIXODENT were safe for their intended use when, in fact, the product was unsafe for its intended use;
- g. In failing to perform appropriate pre-market testing of SUPER POLIGRIP and FIXODENT;
- h. In failing to perform appropriate post-market testing of SUPER POLIGRIP and FIXODENT;
- i. In failing to perform appropriate post-market surveillance of SUPER POLIGRIP and FIXODENT.

79. Defendant(s) knew or should have known that consumers such as Plaintiff(s) herein would foreseeably suffer injury as a result of Defendant(s)' failure to exercise reasonable and ordinary care.

80. As a direct and proximate result of Defendant(s)' carelessness and negligence, and the unreasonably dangerous and defective characteristics of SUPER POLIGRIP and FIXODENT, Plaintiff(s) suffered severe and permanent physical injuries, including but not limited to profound and permanent neurological injuries. Plaintiff(s) have endured substantial pain and suffering. Plaintiff(s) have incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff(s) have suffered a loss of earning capacity. Plaintiff(s) have suffered and will continue to suffer economic loss, and

have otherwise been physically, emotionally/or and economically injured. Plaintiff(s)' injuries and damages are permanent and will continue into the future. The Plaintiff(s) seek actual and punitive damages from Defendant(s) as alleged herein.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT II
(STRICT PRODUCTS LIABILITY – DESIGN DEFECT)

81. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

82. At all times material to this action, Defendant(s) were engaged in the business of formulating, designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling SUPER POLIGRIP and FIXODENT.

83. SUPER POLIGRIP and FIXODENT are defective and unreasonably dangerous to consumers and are defective in their design or formulation in that they are not reasonably fit, suitable, or safe for their intended purposes and/or their foreseeable risks exceed the benefits associated with their design and formulation.

84. At all times material to this action, SUPER POLIGRIP and FIXODENT were distributed from and expected to reach, and did reach, consumers in the Commonwealth of Pennsylvania and throughout the United States, including to Plaintiff(s) herein, without substantial change in the condition in which they were sold.

85. At all times material to this action, SUPER POLIGRIP and FIXODENT were designed, developed, manufactured, tested, packaged,

promoted, marketed, distributed, labeled, and/or sold by Defendant(s) in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, SUPER POLIGRIP and FIXODENT contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff(s) to risks that exceeded the benefits of the product, including but not limited to the risks of developing severe and permanent physical injuries, including but not limited to profound and permanent neurological injuries, as a result of the upset to normal physiologic mineral homeostasis set in motion by excess zinc absorption from metabolized zinc, in an unacceptably high number of its users;
- b. When placed in the stream of commerce, SUPER POLIGRIP and FIXODENT were defective in design and formulation, making the use of SUPER POLIGRIP and FIXODENT more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other denture adhesive products on the market;
- c. When placed in the stream of commerce, SUPER POLIGRIP and FIXODENT were defective in design because the tubes did not have a measurement device, making the use of SUPER POLIGRIP and FIXODENT more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other denture adhesive products on the market;
- d. SUPER POLIGRIP's and FIXODENT's design defects existed before they left the control of Defendant;
- e. SUPER POLIGRIP and FIXODENT were insufficiently tested, *i.e.*, SUPER POLIGRIP and FIXODENT caused harmful side effects that outweighed any potential utility;
- f. SUPER POLIGRIP and FIXODENT were not accompanied by adequate instructions and/or warnings to apprise consumers, including Plaintiff(s) herein, of the full nature and extent of the risks and side effects associated with use of SUPER POLIGRIP and FIXODENT, thereby rendering

Defendant(s) liable to Plaintiff(s), individually and collectively; and

- g. SUPER POLIGRIP and FIXODENT failed to secure Plaintiff(s) dentures in a safe manner and/or without injuries, including without limitation, zinc poisoning, copper deficiency and profound and permanent neurological injuries.

86. In addition, at the time SUPER POLIGRIP and FIXODENT left the control of Defendant(s), there were practical and feasible alternative designs of the formula and/or tubing that would have prevented and/or significantly reduced the risk of Plaintiff(s)' injuries without impairing the reasonably anticipated or intended function of the products. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff(s)' injuries without substantially impairing the utility of SUPER POLIGRIP or FIXODENT.

87. Defendant(s) knew or should have known that the ultimate users or consumers of these products would not, and could not, inspect SUPER POLIGRIP and FIXODENT or otherwise investigate so as to discover the latent defects described above.

88. Plaintiff(s) used SUPER POLIGRIP and FIXODENT to secure their dentures in a manner reasonably foreseeable to Defendant(s), and that manner was reasonably foreseeable by Defendant(s) as involving a substantial danger to Plaintiff(s) and other consumers that was not readily apparent to Plaintiff(s) and consumers, and Defendant(s) failed to provide adequate instructions regarding dosage and use and failed to provide warnings that use of SUPER POLIGRIP and FIXODENT in the manner used would result in adverse health effects to Plaintiff(s) and other consumers.

89. Plaintiff(s) were foreseeable users of SUPER POLIGRIP and FIXODENT.

90. Defendant(s) were or should have been in possession of evidence demonstrating that SUPER POLIGRIP and FIXODENT caused serious adverse health effects.

Nevertheless, Defendant(s) continued to market and sell SUPER POLIGRIP and FIXODENT by providing false, misleading and incomplete information with regard to safety and efficacy of the product.

91. Defendant(s) actions described above were performed willfully, intentionally and with reckless disregard for the rights of Plaintiff(s) and the public.

92. As alleged herein, as a direct and proximate result of Defendant(s)' acts and omissions, and the unreasonably dangerous and defective characteristics of SUPER POLIGRIP and FIXODENT, Plaintiff(s) suffered severe and permanent physical injuries, including but not limited to zinc poisoning, copper deficiency and profound and permanent neurological injuries, for which Defendant(s) are strictly liable. Plaintiff(s) have endured substantial pain and suffering. Plaintiff(s) and his/her spouse have incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff(s) have suffered a loss of earning capacity. Plaintiff(s) have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and/or economically injured. Plaintiff(s)' injuries and damages are permanent and will continue into the future. Plaintiff(s) seek actual and punitive damages from Defendant(s) as alleged herein.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT III
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

93. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

94. SUPER POLIGRIP and FIXODENT were defective and unreasonably

dangerous when they left the possession of Defendant(s) in that they contained warnings insufficient to alert consumers, including Plaintiff(s) herein, of the dangerous risks and reactions associated with SUPER POLIGRIP and FIXODENT including but not limited to their propensity to cause excess zinc in the body resulting in copper depletion and causing profound and permanent neurological and other serious injuries and side effects, notwithstanding Defendant(s)' knowledge of an increased risk of these injuries and side effects over other denture adhesive products containing zinc.

95. Plaintiff(s) purchased and used SUPER POLIGRIP and FIXODENT for their intended purposes.

96. Plaintiff(s) could not have discovered any defect in SUPER POLIGRIP and FIXODENT through the exercise of reasonable care.

97. Defendant(s), as manufacturers and/or distributors of SUPER POLIGRIP and FIXODENT, are held to the level of knowledge of experts in the field.

98. The instructions, directions for use and any warnings that were given by Defendant(s) were inaccurate, unclear and/or ambiguous.

99. The warnings given by Defendant(s) failed to properly warn consumers and Plaintiff(s) of the risk of developing excess zinc in the body from SUPER POLIGRIP or FIXODENT use, resulting in copper depletion and profound and permanent neurological and other serious injuries and side effects.

100. Plaintiff(s) relied upon the skill, superior knowledge and judgment of Defendant(s).

101. Defendant(s) had a continuing duty to warn Plaintiff(s) of the dangers associated with SUPER POLIGRIP and FIXODENT.

102. Had Plaintiff(s) received adequate warnings regarding the risks associated

with using SUPER POLIGRIP and FIXODENT, Plaintiff(s) would not have used the products and/or would have used small amounts of SUPER POLIGRIP and FIXODENT.

103. As alleged herein, as a direct and proximate result of Defendant(s)' acts and omissions, and the unreasonably dangerous and defective characteristics of SUPER POLIGRIP and FIXODENT, Plaintiff(s) suffered severe and permanent physical injuries, including but not limited to profound and permanent neurological injuries. Plaintiff(s) have endured substantial pain and suffering. Plaintiff(s) and their respective spouses have incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff(s) have suffered a loss of earning capacity. Plaintiff(s) have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and/or economically injured. Plaintiff(s) injuries and damages are permanent and will continue into the future. The Plaintiff(s) seek actual and punitive damages from Defendant(s) as alleged herein.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT IV
(BREACH OF IMPLIED WARRANTIES)

104. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

105. Defendant(s) designed, manufactured, marketed, distributed, supplied and sold SUPER POLIGRIP and FIXODENT as denture cream products.

106. At the time that Defendant(s) manufactured, marketed, distributed, supplied, and/or sold SUPER POLIGRIP and FIXODENT, they knew of the use for which SUPER

POLIGRIP and FIXODENT were intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

107. Plaintiff(s) were intended user(s) of SUPER POLIGRIP and FIXODENT and reasonably relied upon the skill, superior knowledge and judgment of Defendant(s).

108. Plaintiff(s) purchased and used SUPER POLIGRIP and FIXODENT for the intended purposes for which they were used -- to improve denture retention and comfort.

109. Due to Defendant(s)' wrongful conduct as alleged herein, Plaintiff(s) could not have known about the nature of the risks and side effects associated with SUPER POLIGRIP and FIXODENT until after she used SUPER POLIGRIP and FIXODENT and was injured.

110. Contrary to the implied warranty for the subject product, SUPER POLIGRIP and FIXODENT were not of merchantable quality, and were not safe or fit for their intended use and purpose, as alleged herein.

111. As alleged herein, as a direct and proximate result of Defendant(s)' acts and omissions, and the unreasonably dangerous and defective characteristics of SUPER POLIGRIP and FIXODENT, Plaintiff(s) suffered severe and permanent physical injuries, including but not limited to profound and permanent neurological injuries. Plaintiff(s) have endured substantial pain and suffering. Plaintiff(s) have incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff(s) have suffered a loss of earning capacity. Plaintiff(s) have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and/or economically injured. Plaintiff(s) injuries and damages are permanent and will continue into the future. The Plaintiff(s) seek actual and punitive damages from Defendant(s) as alleged herein.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of

interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT V
(INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS)

112. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

113. Defendant(s)' conduct directed toward Plaintiff(s), was, by act and omission, intentional, knowing, and/or reckless, and evidenced a willful intention to inflict injury upon Plaintiff(s), or a reckless disregard for the rights and interests of Plaintiff(s) equivalent to an intentional violation of them. This conduct was outrageous and exceeded all bounds usually tolerated by decent and civilized society.

114. As a direct, proximate, intended, known, natural, and foreseeable result of Defendant(s)' conduct, Plaintiff(s) were and are suffering injury in the form of serious, severe, extreme and/or disabling physical injury and emotional distress that no reasonable person could or should be expected to endure.

115. Defendant(s) are liable and accountable at law to compensate Plaintiff(s) for such emotional distress, and for all such damages and injuries resulting therefrom and related thereto.

116. Defendant(s)' conduct was intentional, knowing, oppressive, fraudulent, malicious, extreme and outrageous, and done in conscious and reckless disregard of Plaintiff(s)' rights, thereby entitling Plaintiff(s) to seek to assert claims for exemplary and punitive damages, at the appropriate time under governing law, in an amount sufficient, necessary and appropriate to punish Defendant(s) for their reprehensible conduct and to deter them and others from such conduct in the future. Defendant(s) are liable to Plaintiff(s) jointly and/or severally for all

general, special and equitable relief to which Plaintiff(s) are entitled by law.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT VI
(INEGLIGENT INFLICTION OF EMOTIONAL DISTRESS)

117. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

118. Defendant(s) carelessly and negligently manufactured, marketed, and sold SUPER POLIGRIP and/or FIXODENT to Plaintiff(s), carelessly and negligently concealed these defects from Plaintiff(s), and carelessly and negligently misrepresented the safety and usefulness of SUPER POLIGRIP and FIXODENT. Defendant(s) should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons, that might, in turn, result in illness or bodily harm.

119. Defendant(s) owed a duty to consumers, including Plaintiff(s), to accurately and truthfully represent the risks of the SUPER POLIGRIP and FIXODENT including that use could result in zinc poisoning, copper deficiency and neurological disorders that would go undetected and untreated by the medical community in some cases for a period of years. Despite the Defendant(s) knowledge of the zinc problem and resulting illnesses and injuries, Defendant(s) did not disclose or warn Plaintiff(s) of these risks. Defendant(s) breached their duty by misrepresenting and/or failing to adequately warn Plaintiff(s) of the risks associated with using SUPER POLIGRIP and FIXODENT - effects of which Defendant(s) knew or in the exercise of diligence should have known.

120. As a direct and proximate result of Defendant(s)' wrongful conduct and breach of duty, Plaintiff(s) have sustained and will continue to sustain severe emotional distress due to physical injury that could have been prevented had Defendant(s) warned of the potential for zinc poisoning from SUPER POLIGRIP and FIXODENT, and Plaintiff(s) are entitled to recovery of damages in an amount to be proven at trial. Defendant(s) are liable to Plaintiff(s) jointly and/or severally for all general, special and equitable relief to which Plaintiff(s) are entitled by law.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT VII
(VIOLATION OF PENNSYLVANIA'S CONSUMER PROTECTION ACT)

121. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

122. Defendant(s) engaged in consumer-oriented, consumer commerce and trade, including advertising, offering for sale, sale or distribution of tangible or personal property by selling, distributing and/or advertising SUPER POLIGRIP and FIXODENT.

123. The Commonwealth of Pennsylvania enacted the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.* (the "Consumer Protection Act") to protect consumers from unfair or deceptive acts or practices.

124. SUPER POLIGRIP and FIXODENT were purchased and used primarily for the personal use of Plaintiff(s). Defendant(s)' conduct in connection with their sale of SUPER POLIGRIP and FIXODENT was impermissible and illegal in violation of the Consumer

Protection Act in that Defendant(s) engaged in unfair or deceptive acts or practices by engaging in fraudulent or deceptive conduct which created a likelihood of confusion or of misunderstanding, because Defendant(s) misleadingly, falsely, unconscionably and/or deceptively misrepresented and/or omitted material facts regarding, among other things, the safety of SUPER POLIGRIP and FIXODENT by failing to disclose the risk of zinc poisoning, copper deficiency, hematological injury and/or neurological injury from using SUPER POLIGRIP and FIXODENT in a manner foreseeable and/or intended by Defendant(s). Defendant(s)' conduct violated the Consumer Protection Act and caused Plaintiff(s) an ascertainable loss.

125. The Defendant(s) were or should have been in possession of evidence demonstrating that their product caused and/or has the potential to cause the above side effects, including, e.g., adverse event reports dating as early as 1998 linking denture cream with zinc to injuries similar to Plaintiff(s), adverse events in 2005, and the *Neurology* article in 2008. Nevertheless, Defendant(s) continued to market, sell and distribute SUPER POLIGRIP and FIXODENT without disclosing the above information regarding SUPER POLIGRIP and FIXODENT. As a result, Plaintiff(s) were not warned of the potential for zinc poisoning and other injuries from using SUPER POLIGRIP and FIXODENT, continued to use SUPER POLIGRIP and FIXODENT and suffered ascertainable losses.

126. The Defendant(s) action and inaction described above were performed willfully, intentionally and/or with reckless disregard for the rights and safety of Plaintiff(s) and the public.

127. As a result of Defendant(s)' violations of the Consumer Protection Act, Plaintiff(s) were misled about the unreasonably dangerous and defective characteristics of SUPER POLIGRIP and suffered severe and permanent ascertainable losses, including but not

limited to profound and permanent neurological injuries. Plaintiff(s) have endured substantial pain and suffering. Plaintiff(s) have incurred significant monetary expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff(s) have suffered a loss of earning capacity. Plaintiff(s) have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and/or economically injured. Plaintiff(s) injuries and damages are permanent and will continue into the future. Plaintiff(s) seek actual and punitive damages from Defendant(s) as alleged herein.

128. The Plaintiff(s) are entitled to treble damages because the Defendant(s)' failure to warn was reckless, egregious and unconscionable. The Defendant(s) misled the public at large, including the Plaintiff(s), by their knowing concealment, suppression, or omission of material facts about the safety of their products. The Defendant(s) downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of SUPER POLIGRIP and FIXODENT despite available information demonstrating that this product was likely to cause serious side effects to users.

129. Accordingly, the Plaintiff(s) seek and are entitled to actual damages and treble damages in an amount to be determined at trial.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT VIII
(VIOLATION OF STATE CONSUMER FRAUD ACTS)

130. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

131. Defendant(s) had a statutory duty to refrain from unfair or deceptive acts or

practices in the design, development, manufacture, promotion and sale of SUPER POLIGRIP and FIXODENT.

132. Had Defendant(s) not engaged in the deceptive conduct described above, Plaintiff(s) would not have purchased and/or paid for SUPER POLIGRIP and FIXODENT, would not have incurred related medical costs and expenses and would not have incurred the attorneys' fees and costs alleged herein.

133. Defendant(s)' deceptive, unconscionable or fraudulent representations and material omissions to Plaintiff(s) constituted unfair and deceptive acts and practices in violation of the state consumer protection statutes listed below.

134. Defendant(s) engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff(s) for SUPER POLIGRIP and FIXODENT that they would not have paid had Defendant not engaged in unfair and deceptive conduct.

135. Defendant(s)' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes, as listed below:

- i. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;
- ii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;
- iii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;
- iv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;
- v. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code § 1770, *et seq.* and Cal. Bus. & Prof. Code § 17200, *et seq.*;

- vi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;
- vii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-11 Oa, *et seq.*;
- viii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §§ 2511, *et seq.* and 2531, *et seq.*;
- ix. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq.*;
- x. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;
- xi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §§ 10-1-372, *et seq.*, 10-1-392 and 10-1-420.
- xii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, *et seq.*;
- xiii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-60 1, *et seq.*;
- xiv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;
- xv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, *et seq.*;
- xvi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16, *et seq.*;
- xvii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;
- xviii. Defendant(s) have engaged in unfair competition or unfair

or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.170, *et seq.*;

- xix. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;
- xx. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 205A, *et seq.*;
- xxi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;
- xxii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;
- xxiii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann.. § 445.901, *et seq.* ;
- xxiv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325D.43, *et seq.*; 325F.67, *et seq.*; and 325F.68 *et seq.*;
- xxv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;
- xxvi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Ann. Missouri Stat. § 407.0 10, *et seq.*;
- xxvii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann. § 30-14-101, *et seq.*;
- xxviii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;
- xxix. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. § 598.0903, *et seq.*;
- xxx. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

- xxxi. Defendant(s) have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et seq.*;
- xxxii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*;
- xxxiii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§ 349 *et seq.* and 350-e, *et seq.*;
- xxxiv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;
- xxxv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§ 51-12-01, *et seq.*, and 51-15-01, *et seq.*;
- xxxvi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;
- xxxvii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq.*;
- xxxviii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;
- xxxix. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;
- xl. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;
- xli. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;
- xlii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-1, *et seq.*;
- xliii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code §

47-18-101, *et seq.*;

- xliv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;
- xlv. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, *et seq.*;
- xlvi. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq.*;
- xlvii. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;
- xlviii. Defendant(s) have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et seq.*;
- xlix. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.* ;
 - 1. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*; and
 - li. Defendant(s) have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-101, *et seq.*

136. Plaintiff(s) were injured by the cumulative and indivisible nature of Defendant(s)' conduct. The cumulative effect of Defendant(s)' conduct directed at consumers was to create demand for and sell SUPER POLIGRIP and FIXODENT. Each aspect of Defendant(s)' conduct combined to artificially create sales of SUPER POLIGRIP and FIXODENT.

137. Plaintiff(s) relied upon Defendant(s)' misrepresentations and/or omissions in determining which denture cream to purchase and the amount of denture cream to purchase.

138. By reason of the unlawful acts engaged in by Defendant(s), Plaintiff(s) have

suffered ascertainable loss and damages.

139. As a direct and proximate result of Defendant(s)' wrongful conduct, Plaintiff(s) were damaged by paying for SUPER POLIGRIP and FIXODENT.

140. As a direct and proximate result of Defendant(s)' conduct, Plaintiff(s) have incurred the cost of SUPER POLIGRIP and FIXODENT and related medical costs including testing and evaluation for zinc poisoning, copper deficiency and neurological disorders, copper supplementation, physical therapy and/or other hospital costs, in an amount to be proven at trial.

141. As a direct and proximate result of Defendant(s)' wrongful conduct, Plaintiff(s) are entitled to compensatory damages, treble damages, attorneys' fees, and costs of suit.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT IX
(COMMON LAW FRAUD)

142. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

143. Contrary to Defendant(s)' representations to Plaintiff(s), SUPER POLIGRIP and FIXODENT could cause severe injury or death. At all times during the course of dealing between Defendant(s) and Plaintiff(s), Defendant(s) misrepresented that SUPER POLIGRIP and FIXODENT were safe and effective for their intended use by affirmative misrepresentation; actively concealed and knowingly or recklessly omitted material facts regarding the safety and effectiveness of the SUPER POLIGRIP and FIXODENT; and/or by their course of conscious or intentional conduct succeeded in selling and marketing SUPER POLIGRIP and FIXODENT.

144. Defendant(s), by concealment or other actions, intentionally prevented Plaintiff(s), Plaintiff(s)' physicians, and Plaintiff(s)' other agents from acquiring material information regarding the lack of safety and effectiveness of SUPER POLIGRIP and FIXODENT and prevented Plaintiff(s) from acquiring material information about Plaintiff(s) injuries that would have prevented the Plaintiff(s) from undergoing years of pain and suffering from zinc poisoning from SUPER POLIGRIP and FIXODENT. Defendant(s) are subject to the same liability to Plaintiff(s) for Plaintiff(s)' pecuniary losses, as though Defendant(s) had affirmatively stated the non-existence of such matters that Plaintiff(s) were thus prevented from discovering, and therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts § 550 (1977)*.

145. Defendant(s) were under a duty and failed to discharge their duty to exercise reasonable care to disclose to all Plaintiff(s) the defective nature of SUPER POLIGRIP and FIXODENT, of which they had special knowledge about the risks of using SUPER POLIGRIP and FIXODENT, including the risk of developing zinc poisoning, copper deficiency and related injuries, that were not available to Plaintiff(s), and as to which Defendant(s) have made affirmative misrepresentations in violation of all applicable laws, including, *inter alia*, *Restatement (Second) of Torts § 551 (1977)*.

146. Defendant(s)' misrepresentations, concealment, suppression and omissions were made willfully, wantonly, uniformly, deliberately or recklessly, in order to induce Plaintiff(s) to purchase SUPER POLIGRIP and FIXODENT and Plaintiff(s) did reasonably and justifiably rely upon the material misrepresentations and omissions made by the Defendant(s) about the SUPER POLIGRIP and FIXODENT when purchasing the products.

147. As a direct and proximate result of Defendant(s)' fraudulent conduct, Plaintiff(s) have suffered personal injuries and/or pecuniary losses and economic damages in an

amount to be proven at trial. Defendant(s) are jointly and severally liable to Plaintiff(s) for all relief to which Plaintiff(s) are entitled by law.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT X
(LOSS OF CONSORTIUM)

148. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

149. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) necessarily paid and has (have) become liable to pay for medical aid, treatment, attendance, and medications, and will necessarily incur further expenses of a similar nature in the future.

150. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) been caused presently and in the future the lost of his/her (wife, husband, child)'s companionship, services, and society.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT XI
(SURVIVAL ACTION)

151. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

152. As a direct and proximate result of the conduct of Defendant(s) outlined

above, Decedent Plaintiff(s) suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to Decedent Plaintiff(s)' deaths.

153. The representatives/administrators of Decedent Plaintiff(s)' estate bring this claim on behalf of Decedent Plaintiff(s)' estate and Decedent Plaintiff(s)' beneficiaries for damages.

154. The representatives/administrators of Decedent Plaintiff(s)' estate further pleads all survival damages allowed by statute in the state or states in which the causes of action accrued.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

COUNT XII
(GROSS NEGLIGENCE AND MALICE)

155. Plaintiff(s) incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein and further allege as follows.

156. The wrongs done by Defendant(s) were aggravated by the kind of malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiff(s) for which the law would allow, and which Plaintiff(s) will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendant(s)' conduct: was specifically intended to cause substantial injury to Plaintiff(s); or when viewed objectively from Defendant(s)' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendant(s) were actually and/or subjectively

aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendant(s) knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff(s).

157. Plaintiff(s) relied on Defendant(s)' representations and suffered injury as a proximate result of this reliance.

158. Plaintiff(s) therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court. Plaintiff(s) also allege that the acts and omissions of named Defendant(s), whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff(s). In that regard, Plaintiff(s) will, as noted, seek exemplary damages in an amount that would punish Defendant(s) for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff(s) pray for judgment against Defendant(s), jointly and severally, in compensatory and punitive damages in an amount in excess of \$50,000.00, exclusive of interest and allowable costs of suit, which will compensate the Plaintiff(s) for their injuries and deter the Defendant(s) and others from like conduct.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff(s) pray for judgment against each of the Defendant(s), individually and jointly, as follows:

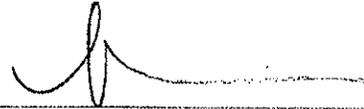
- a. Awarding actual damages to the Plaintiff(s) incidental to Plaintiff(s)' purchases and use of SUPER POLIGRIP and FIXODENT in an amount to be determined at trial;
- b. Awarding treble and/or punitive damages to the Plaintiff(s);
- c. Awarding pre-judgment and post-judgment interest to the Plaintiff(s);

- d. Awarding the costs and the expenses of this litigation to the Plaintiff(s);
- e. Awarding of loss of consortium damages to each Plaintiff;
- f. Awarding reasonable attorneys' fees and costs to the Plaintiff(s) as provided by law; and
- g. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff(s) hereby demand a trial by Jury on all Counts and as to all issues.

Dated: October 19, 2009



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Michelle L. Tiger, Esquire/43872
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**IN RE: DENTURE ADHESIVE CREAM
LITIGATION**

**PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION**

June Term, 2009

No. 4534

2009 OCT 20 PM 4:14

In Re: Denture Adhesive Cream-I.FCMP

NOTICE TO PLEAD



09060453400005

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Lawyer Referral Service
Philadelphia Bar Association
1101 Market Street, 11th Floor
Philadelphia, PA 19107
(215) 238-6338

ADVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ESTA OFICINA LO PUEDE PROPORCIONAR CON INFORMACION ACERCA DE EMPLEAR A UN ABOGADO. SI USTED NO PUEDE PROPORCIONAR PARA EMPLEAR UN ABOGADO, ESTA OFICINA PUEDE SER CAPAZ DE PROPORCIONARLO CON INFORMACION ACERCA DE LAS AGENCIAS QUE PUEDEN OFRECER LOS SERVICIOS LEGALES A PERSONAS ELEGIBLES EN UN HONORARIO REDUCIDO NINGUN HONORARIO.

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Denture cream

An unusual source of excess zinc, leading to hypocupremia and neurologic disease



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ABSTRACT

Background: Chronic, excess zinc intake can result in copper deficiency and profound neurologic disease. However, when hyperzincemia is identified, the source often remains elusive. We identified four patients, one previously reported, with various neurologic abnormalities in the setting of hypocupremia and hyperzincemia. Each of these patients wore dentures and used very large amounts of denture cream chronically.

Objective: To determine zinc concentration in the denture creams used by the patients as a possible source of excess zinc ingestion.

Methods: Detailed clinical and laboratory data for each patient were compiled. Tubes of denture adhesives were analyzed for zinc content using dynamic reaction cell-inductively coupled plasma-mass spectrometry. Patients received copper supplementation. Copper and zinc levels were obtained post-treatment at varying intervals.

Results: Zinc concentrations ranging from about 17,000 to 34,000 $\mu\text{g/g}$ were identified in Fixodent and Poli-Grip denture creams. Serum zinc levels improved in three patients following cessation of denture cream use. Copper supplementation resulted in mild neurologic improvement in two patients who stopped using denture cream. No alternative source of excess zinc ingestion or explanation for hypocupremia was identified.

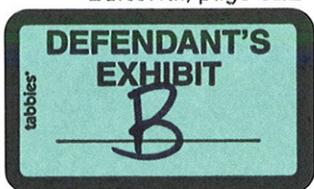
Conclusion: Denture cream contains zinc, and chronic excessive use may result in hypocupremia and serious neurologic disease. *Neurology* 2008;71:639-643

GLOSSARY

Hct = hematocrit; MRC = Medical Research Council; NCS = nerve conduction study; WBC = white blood cell.

Copper deficiency is a well-established and increasingly recognized cause of neurologic and hematologic disease.^{1,2} The most common neurologic manifestations of copper deficiency include myelopathy with or without peripheral neuropathy.¹⁻³ Less frequently reported, and less clearly causally associated with hypocupremia, are motor neuron disease,⁴ peripheral neuropathy in the absence of myelopathy,^{5,6} and optic neuritis.⁵ Acquired copper deficiency can result from gastrointestinal surgery, malabsorption, and parenteral feeding deficiency.¹ In addition, excess zinc ingestion has also been established as a cause of hypocupremia.^{1,2} We describe four patients with various neurologic abnormalities who reported chronic use of extremely large amounts of denture cream. The neurologic symptoms of one patient were previously reported in an article focusing on hematologic disease in zinc-induced copper deficiency.⁷ Laboratory evaluation revealed hypocupremia, hypoceruloplasminemia, and hyperzincemia in all four patients. In this investigation, we sought to test the hypothesis that excessive use of denture cream was the source of hyperzincemia and hypocupremia. Three formulations of denture cream, including the ones used by our patients, were analyzed for zinc content by dynamic reaction cell-inductively coupled plasma-mass spectrometry. Data from initial and follow-up neurologic, electrodiagnostic, and laboratory testing were also compiled.

Editorial, page 622



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From the Departments of Neurology (S.P.N., L.A.L., G.I.W., J.R.T.) and Clinical Sciences (L.S.H., J.R.), University of Texas Southwestern Medical Center, Dallas; the Department of Pathology (P.J.B.), University of Colorado Health Sciences Center; and the Department of Laboratory Medicine and Pathology (M.F.B., J.A.B.), Mayo Clinic, Rochester, MN.

Disclosure: The authors report no disclosures.

Table 1 Characteristics of patients using excessive amounts of denture cream

	Case 1	Case 2	Case 3	Case 4*
Age, y	41	44	61	42
Sex	F	F	M	M
Symptoms/signs	3.5 years limb weakness, spasticity, incontinence, poor cognition	7 months distal weakness/atrophy, paresthesias, hyperreflexia	1 year ascending paresthesias, ataxia, vibratory and proprioceptive loss	8 months sensory ataxia, hyperreflexia, distal weakness
Serum copper (0.75-1.45 µg/mL)	<0.1	0.18	0.23	<0.1
Ceruloplasmin (22.9-43.1 mg/dL)	0.6	3.0	6.2	1.1
Serum zinc (0.66-1.10 µg/mL)	2.0	1.36	1.4	4.28
CSF protein (15-45 mg/dL)	34	59	56	97
WBC count (4.1-11.1 × 10 ³ /µL)	3.6	7.2	10.3	2.9
Hematocrit (female: 36.8-48.7%; male: 39.6-50.2%)	48.3	46.2	37.7	34.8
NCS/EMG	Normal	Axonal motor neuropathy, active denervation distally	Axonal sensorimotor polyneuropathy	Low sural amplitude
MRI, brain and spinal cord	Normal	Bilateral subcortical hyperintense T2 abnormalities	Normal	Normal
Clinical and laboratory response to Cu supplementation	Improved cognition, incontinence, and sensation, Cu 3.39, Zn 1.38	Improved distal strength, sensation normalized, Cu 0.86, Zn 0.98	No change,† Cu 0.84, Zn 1.33	Improved hematologic parameters; no neurologic improvement, Cu 1.15, Zn 1.29

*Some of the clinical features of this patient were reported previously.⁷

†Patient continued denture cream use.

WBC = white blood cell; Hct = hematocrit; NCS = nerve conduction study.

METHODS All sample preparations and analyses were conducted at the Mayo Clinic, Rochester, MN, in a Class 10,000 clean room engineered specifically for metal analysis in clinical specimens.

Serum zinc and copper measurements. Evaluation of serum samples from all patients was performed using standard clinical techniques.

Denture cream analysis. Tubes of major brands of denture adhesive (Fixodent Original [n = 5], Super Poli-Grip Original [n = 6], and Super Poli-Grip Extra Care with Polyscal [n = 5]) were purchased in retail stores in Dallas, TX, and Rochester, MN. Lot numbers were different for each tube analyzed. Zinc concentrations were analyzed in duplicate on two separate days for a total of four measurements from each tube of denture cream by dynamic reaction cell-inductively coupled plasma-mass spectrometry (DRC II, Perkin Elmer Instrument, Shelton, CT).⁸

Case reports. The clinical, laboratory, and radiologic findings of the four patients described in this study are summarized in table 1. A detailed summary of patients 1 and 2 is provided to illustrate both typical and atypical features of these cases.

Case 1. A 41-year-old woman presented with a 3.5-year history of numbness and weakness of the arms and legs, progressing to wheelchair dependence. She later developed urinary incontinence and mild cognitive decline. Two years before the onset of her leg weakness, she started wearing dentures and used denture cream, typically two tubes every week. Examination revealed distal greater than proximal weakness, extensor plantar responses, decreased perception of pinprick to the hips, and decreased vibratory sensation and proprioception to the ankles. MRI of the neuraxis was normal. Nerve conduction studies (NCS) and needle electromyography were normal. CSF analysis,

routine biochemistry, vitamin B12 studies, and HIV studies were normal. Complete blood count was normal except for white blood cell count of $3.6 \times 10^3/\mu\text{L}$ (4.1-11.1). Serum copper was $<0.1 \mu\text{g/mL}$ (0.75-1.45), serum ceruloplasmin was 0.6 mg/dL (22.9-43.1), and serum zinc was $2.00 \mu\text{g/mL}$ (0.66-1.10). She received IV copper supplementation at a dose of 2 mg daily for 5 days followed by oral supplementation. Six weeks after copper supplementation and discontinuation of denture cream, she reported improved sensation, strength, sphincter control, and cognition. Proximal lower extremity strength had improved from Medical Research Council (MRC) grade 3 to 4. Zinc level had improved to $1.38 \mu\text{g/mL}$ and copper was $3.39 \mu\text{g/mL}$.

Case 2. A 42-year-old woman presented with a 7-month history of asymmetric hand weakness, most prominent in finger extensors. She also had hand numbness and poor balance. She had worn dentures for many years and used about three tubes of denture cream per week. Her examination revealed severe distal upper extremity weakness and atrophy, distal greater than proximal weakness of the lower extremities, hyperreflexia, extensor plantar responses, and decreased pinprick sensation in the hands. Vibratory sensation and proprioception were normal. Brain MRI showed confluent bifrontal subcortical hyperintense abnormalities on T2 and diffusion-weighted images. MRI of the spine was normal. CSF analysis was unremarkable apart from mildly elevated protein of 59 mg/dL. Serologic testing for HIV, HTLV1 and 2, Lyme, and syphilis was negative. Antinuclear antibodies, erythrocyte sedimentation rate, angiotensin converting enzyme, arylsulfatase A, very long chain fatty acids, serum B12, methylmalonic acid, 24-hour urine heavy metal screen, and plasma porphyrins were normal or negative. NCS and EMG demonstrated an axonal motor neuropathy with active denerva-

Table 2 Zinc concentration in denture creams measured by dynamic reaction cell-inductively coupled plasma-mass spectrometry

Denture creams analyzed	Zinc, $\mu\text{g/g}$ (SD)
Fixodent, Original (n = 5)	17,283.65 (1,724.03)
Poli-Grip, Original (n = 6)	34,190.94 (1,781.21)
Poli-Grip, Polyseal (n = 5)	27,531.53 (1,554.76)

n = Number of tubes analyzed.

tion in distal muscles. Serum copper was 0.18 $\mu\text{g/mL}$, ceruloplasmin was 3.0 mg/dL, and serum zinc was 1.36 $\mu\text{g/mL}$. The patient was treated with IV copper followed by oral supplementation. She also stopped using denture cream. Six months later, distal hand strength had improved from MRC grade 0 to 2. Copper level was 0.86 $\mu\text{g/mL}$ and zinc was 0.98 $\mu\text{g/mL}$.

Cases 3 and 4. Two other patients presented with typical features of myeloneuropathy, hypocupremia, and hyperzincemia in the setting of denture cream use. For patient 4, hematopathologic findings and a summary of neurologic findings have been previously reported.²

RESULTS Concentrations of zinc in denture creams as determined by dynamic reaction cell-inductively coupled plasma-mass spectrometry are summarized in table 2. The relatively small standard deviations among the multiple measurements of zinc made for each brand argue strongly against contamination, a serious obstacle to accurate trace metals analysis.

DISCUSSION Copper is an essential trace metal, critical to multiple biologic processes including the function of numerous enzymes.⁹ Copper deficiency is known to cause neurologic and hematologic disease.^{1, 7,10-12} Clinical findings of myeloneuropathy associated with copper deficiency resemble those in subacute combined degeneration due to vitamin B12 deficiency.^{1,2} Typical findings include spastic gait, ataxia, and marked dorsal column deficits. While the mechanism by which hypocupremia leads to neurologic abnormality in humans remains uncertain, a similar copper deficiency-associated myelopathy has been documented in domesticated ruminants (swayback disease).¹³ Rarely, neurologic manifestations may occur in the absence of hematologic involvement.³

Copper deficiency can arise in a variety of clinical settings including malabsorption-associated disease processes (e.g., protein-losing gastroenteropathy,¹⁴ celiac disease,¹⁵ Menkes syndrome^{13,16}), gastrointestinal surgery,^{1,2,10} dietary deficiency (e.g., enteral or total parenteral nutrition^{1,17}), and use of copper chelating agents.¹⁸ Ingestion of excess zinc in the form of zinc supplements, denture cream, and coins has also been associated with copper deficiency.^{7,11,19,20} Absorption of copper and zinc from ingested material and from salivary, gastric, biliary, and

pancreatic secretions occurs by way of specific transporter proteins in small bowel enterocytes. Other transporter proteins regulate metal localization within organelles and efflux into the bloodstream. The labile intracellular pool of the metals is bound by metallothionein, which has a higher affinity for copper than zinc. Excess zinc ingestion upregulates metallothionein production which preferentially sequesters copper in the enterocyte, effectively reducing copper uptake into the body, and ultimately increasing fecal loss.^{9,21-23} Treatment of Wilson disease with oral zinc exploits this copper chelating mechanism.²³

We report three new patients and summarize neurologic findings on one previously reported patient (patient 4)² in whom hypocupremia and hyperzincemia were identified. Each patient wore dentures and used two or more tubes of denture cream per week for years. Evaluation of past medical, surgical, and family history and thorough laboratory testing failed to disclose any other process that could explain the neurologic abnormalities in these patients. Zinc concentrations ranging from about 17,000 to 34,000 $\mu\text{g/g}$ were identified in the brands of denture cream used by our patients. No other plausible explanation for zinc excess or copper deficiency was identified. Serum zinc levels improved in three patients with cessation of denture cream use, strongly supporting denture cream as the source of this metal. In contrast, patient 3 continued to use denture cream, and his zinc level remained elevated. Copper supplementation resulted in normalization of copper levels in all four patients, but mild neurologic improvement was noted in only two patients.

The literature currently documents at least 43 patients with myelopathy, peripheral neuropathy, or myeloneuropathy in whom laboratory evaluation identified hypocupremia. The exact number of cases is difficult to determine as some patients have been included in two or more reports. Of the 32 patients for whom serum or urine zinc levels were reported, 25 patients (78%) had elevated values.^{1,2,3,7,11,12,24,31} Notable with respect to accurate laboratory screening for excess zinc intake and excretion, 4 patients with normal serum levels had elevated 24-hour urine levels.² However, the source of the hyperzincemia or hyperzincuria was identified in only 4 patients, with a presumed denture cream source noted in one patient (our patient 4)² and zinc supplement source noted in three others.^{2,4,6,11}

Although tooth loss has declined in the United States due to improved preventive dental care and fluoridation of drinking water, many individuals, especially the elderly, wear dentures. Denture adhesive is used to optimize the fit and improve retentive

qualities of a dental prosthesis and thus improve chewing ability and comfort.^{25,26} Few studies have attempted to document the proportion of individuals who wear dentures or the rate of denture adhesive use among denture wearers. It has been estimated that between 6.9 and 33% of denture wearers regularly use denture adhesive, but these data are based in part on an unpublished survey and industry estimates.^{25,26} In a study of 146 denture wearers in South Australia, 32.9% had tried denture adhesive and 6.9% used it on a regular basis; of these, most adhesive users were in the 50–80 years age group.²⁶ Recommended instructions for use include application of thin strips or series of dots. With once daily application of a typical amount of 0.5 to 1.5 g per dental unit,²⁴ a 68 g tube would last about 3 to 10 weeks. In our report, three of the four patients are very atypical in that their edentulous state occurred at a younger age and each used extremely large amounts of denture adhesive daily for years.

Using inductively coupled plasma mass spectrometry, a sensitive and specific technique for the determination of metal content,⁸ varying concentrations of zinc were detected in the brands of denture cream used by our patients. Modern denture creams employ calcium-zinc polymers which, with hydration by saliva, establish adhesive and cohesive properties.²⁵ The polymer is solubilized and adhesiveness is reduced, with the effect increased by hot liquids, possibly requiring reapplication.²⁵ Inevitably, some of the adhesive is swallowed by the user. Each of our patients used two tubes or more of denture cream per week to optimize the fit of his or her dentures. In addition, patient 4 ingested “pellets” of denture cream. We speculate that the copper deficiency in these four patients was secondary to ingestion of denture cream. Although the patients applied denture cream generously, the amount of ingested zinc cannot be calculated. However, we do know that the denture creams used by the patients in this study contain at least 17 mg of zinc per gram of cream, and application of two standard 68 g tubes or more per week would lead to exposure of at least 330 mg of zinc per day. It is reasonable to assume that the patients’ ingestion of zinc exceeded the NIH’s recommended daily allowance for adult women (8 mg) and men (11 mg) and may have also exceeded the daily tolerable upper level intake of 40 mg established in 2001 by the National Academy of Sciences.²⁷

While the neurologic disease in our patients is most likely the result of acquired copper deficiency, a direct neurotoxic effect of elevated zinc cannot be ruled out. Experimental studies in cell culture, isolated mitochondria, and animal models have demonstrated an apparent neurotoxic effect of excess zinc

with excitotoxic, apoptotic, and mitochondrial inhibitory pathogenic mechanisms proposed.^{9,22} However, no similar evidence has been reported to date in humans. Most notably, no clinical abnormalities have been identified in affected individuals in two families with hereditary hyperzincemia, and serum copper levels were normal in those affected individuals in whom it was measured.^{28–30}

Some atypical clinical features were present in two of our patients. Patient 1 experienced mild cognitive impairment which improved following copper supplementation. Her cognition was not formally evaluated prior to therapy, and therefore we do not have quantitative data to support this improvement. The significance of this finding is uncertain and does not necessarily imply a causal relationship with hypocupremia. Another unusual feature was seen in patient 2 who had predominantly motor, asymmetric weakness, involving the upper extremities more than the lower extremities simulating a motor neuron disease. This phenotype was recently reported in three patients with hypocupremia.⁴

Whether the white matter abnormality noted on MRI evaluation in the brain of patient 2 is the result of hypocupremia or another, currently undisclosed etiologic process is uncertain. The most consistent abnormal finding on spine MRI in patients with copper deficiency myelopathy is increased T2 signal in the dorsal columns. The cervical cord is most commonly involved, and contrast enhancement is not present.^{3,12} Several other reports have documented either brain or spinal cord myelin abnormalities on MRI in the setting of copper deficiency-associated neurologic disease,^{1,3,31,32} and ingestion of the copper chelator cuprizone has been used as a model of CNS demyelination.³³

This report quantitates the zinc content in commercially available denture creams. It also documents a possible association between markedly excessive denture cream use and hyperzincemia, secondary hypocupremia, and subsequent neurologic symptoms. These findings, while not proving a causal relationship, warrant routine inquiry about the use of denture cream, in addition to zinc supplements, during the clinical evaluation of patients with myeloneuropathy and hematologic dysfunction. Patients should also be advised to seek professional care if they require increasing amounts of denture adhesive for ill-fitting dentures.

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Denture cream: An unusual source of excess zinc, leading to hypocupremia and neurologic disease

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