COMMENTARY

Denture Cream: Fixodent or Forget It?

By Courtney Ward-Reichard, Esq.

In August 2008 an article in the medical journal Neurology reported the results of a study finding that excessive use of denture creams containing zinc, on the order of two to three tubes per week, caused adverse health effects in four patients.[1] Even though the study was small and involved patients using very large amounts of the product, it led to the filing of numerous product liability claims within just a few months. Many more suits are expected as plaintiffs' law firms seek to sign up new clients among the estimated 35 million denture cream users.

In July the Judicial Panel on Multidistrict Litigation consolidated over a dozen federal claims in the U.S. District Court for the Southern District of Florida, including two purported class actions filed in Tennessee. All these cases, but the class actions in particular, face an uphill battle. This commentary discusses the background and status of the denture cream litigation and analyzes the likelihood that these cases (particularly the class actions) will succeed.

Denture Cream and Zinc

Zinc is a beneficial substance to the body and is often taken as a dietary supplement or cold remedy. It sometimes is used in denture cream to improve its adhesive strength. However, over-absorption of zinc can cause copper deficiency, or hypocupremia, that in turn can cause nerve damage, neuropathy, pain, paralysis or neurological problems.

The study reported in Neurology was conducted at the University of Texas Southwestern Medical Center. Only four patients were studied, and all had symptoms such as limb weakness and poor balance. All four also used very large amounts of denture cream (at least two tubes per week) because of ill-fitting dentures for a number of years.

The article detailed the histories of two of the patients: one was a 41-year-old woman "with a three-and-a-half-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. Six weeks after copper supplementation and discontinuation of denture cream, she reported improved sensation, strength, sphincter control and cognition."[2]

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The other patient was a 42-year-old woman with "a seven-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. 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 µg/mL and zinc was 0.98 µg/mL."[3]

The researchers acknowledged that three of the four study participants were "very atypical" in that they began wearing dentures at a young age and "each used extremely large amounts of denture adhesive daily for years."[4] The study also acknowledged that it was not possible to measure the amount of zinc ingested by each of the patients. Instead, researchers measured the zinc content of the denture cream they used, estimating that the patients were absorbing many times the recommended daily allowance of zinc, and concluding that over-absorption of zinc caused the patients' symptoms. Finally, it was noted in a subsequent letter to Neurology that many patients showing signs of copper deficiency had additional factors combined

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with exposure to excess zinc, including gastric surgery, malnutrition or other malabsorption syndromes.[5]

Denture Cream Lawsuits Take Off, Are Consolidated

This research was not the first case study of zinc toxicity stemming from the use of denture cream, but it was the first one that was widely reported in the popular media. Fixodent and Super Poligrip are the two major brands of denture cream that contain zinc. They are manufactured by Proctor & Gamble and GlaxoSmithKline, respectively. The first lawsuits against the manufacturers were brought by individuals claiming adverse health effects as a result of using the creams.

All denture cream lawsuits pending in federal courts were consolidated June 9 in an MDL before U.S. District Judge Cecilia M. Altonaga of the Southern District of Florida. There are at least 18 current claims in the MDL, and future claims made in federal court will be transferred to the MDL.

Proctor & Gamble opposed the consolidation, arguing that "the actions do not share sufficient questions of fact because individual issues will predominate, such as each plaintiff's medical and dental histories and conditions, the specific injury or disease alleged, each plaintiff's denture cream use, and other sources of zinc ingestion."[6] GlaxoSmithKline did not join in opposing the MDL, though it sought a different forum for the litigation.

The JPML held: "While these arguments have some merit, on balance they are unconvincing. Transfer under 28 U.S.C.A. § 1407 does not require a complete identity or even a majority of common factual or legal issues as a prerequisite to transfer."[7]

Next Step: Class Action

Two denture cream class-action lawsuits were filed in the Western District of Tennessee March 10, one against Proctor & Gamble[8] and one against GlaxoSmithKline.[9] These suits seek to certify classes consisting of all Tennessee residents who purchased and used the denture creams. The requested remedy was medical monitoring and treatment as required for all class members. Both actions were transferred to the MDL.

These actions should face significant barriers to class certification. First, there are numerous individual issues among the proposed class members, including the amount of denture cream used, other sources of zinc exposure and previous medical history. Similar arguments were made in opposition to the MDL. Although the JPML said these arguments had "some merit," it ultimately held that transfer "does not require a complete identity or even a majority of common factual issues as a prerequisite."[10] However, this standard is not as stringent as the requirements under Federal Rule of Civil Procedure 23.

In fact, the predominance of individual issues has been a frequent barrier to class-action certification in the mass-tort context. When Rule 23 was revised in 1966, the Civil Rules Advisory Committee noted that a mass accident "is ordinarily not appropriate for a class action because of the likelihood that significant questions, not only of damages but of liability and defenses to liability, would be present, affecting the individuals in different ways."[11] As many courts have noted, this means "issues common to the class must predominate over individual issues."[12] While there may be some common issues with respect to warnings issues, the individual issues pertaining to causation will far outweigh any common concerns of the class.

In January 2008 U.S. District Judge John F. Keenan of the Southern District of New York denied certification of three medical monitoring classes in drug litigation, citing the need for individualized proof.[13] The product at issue in these cases was the drug Fosamax, used to prevent osteoporosis. The plaintiffs alleged the use of Fosamax caused a painful, degenerative bone condition called osteonecrosis of the jaw. As with the denture cream suits, many individual claims were filed in addition to three class actions. The class-action plaintiffs sought certification of statewide medical monitoring classes that included people who had used Fosamax but were not diagnosed with ONJ. The plaintiffs sought a medical monitoring program under which each member of the class would receive comprehensive dental examinations twice a year and ONJ screenings.

Judge Keenan denied class certification, noting that the proposed class definition "did not set any dosage limitations on class membership," "attempt to screen individuals with unique risk factors for ONJ," or "specify the duration of the proposed dental monitoring program."[14] He also concluded that the plaintiffs could not demonstrate many of Rule 23's required elements.[15]

Typicality was lacking because "almost every element of a medical monitoring claim will require highly individualized proof of each class member's medical condition in the circumstances of their use of Fosamax."[16] As in the denture cream cases, the determination of whether any individual was at greater risk for ONJ depended upon duration and dosage, medical history, and other risk factors.

Judge Keenan also found that the class representatives could not adequately represent the interests of the class because of the "inherent differences" in their claims. As

a result, it was "possible that class representatives would rely on arguments that are adverse to the interests of other class members."[17] Finally, he held that a class action was not a superior method to adjudicate the class members' potential claims because "there is an insufficient basis to believe that all class members would prefer the proposed monitoring program to one designed with their own particular circumstances in mind."[18]

In addition to certification issues, the denture cream class actions also will face an uphill battle with respect to causation in general. Tennessee law concerning medical monitoring has been described as "murky"[19] but "most probably proper" under the state's product liability laws. Nevertheless, even if permitted under Tennessee laws, medical monitoring claims require a showing that such monitoring is medically necessary — a showing that will be difficult to make with respect to ordinary users of denture cream.

The original study in Neurology involved people who used extremely high amounts of denture cream, and all the individual suits filed so far appear to involve similar, excessive usage. In stark contrast, the proposed class actions involve claims of all users of denture cream containing zinc, regardless of the amount of individual use. There is no scientific evidence suggesting that ordinary use of zinc-containing denture cream causes any adverse health effects. Proctor & Gamble says "the amount of zinc an average denture adhesive user would ingest from daily usage of Fixodent is less than the amount of zinc in most daily multivitamins, less than six oysters (fried or raw) and comparable to 6 oz. ground beef."[20]

In fact, the class representatives do not allege any present injury. Instead, they seek to establish medical monitoring for members of the class to determine whether they have been injured. Courts have long struggled with claims for medical monitoring, for such a claim inherently involves claimants who have no manifest injury, in essence seeking "to recover the anticipated costs of long-term, diagnostic testing necessary to detect latent diseases that may develop as a result of tortious exposure to toxic substances."[21]

So, what's next? It is likely that more class-action and individual suits will be filed. An Internet search for "denture cream lawsuit" turns up a myriad of Web sites seeking to recruit plaintiffs, such as www.DentureCreamLawyer.com, www.ZincPoisoning.com, www.DentureCreamInjuryLawyerInfo.com, www.DentureCreamSickness.com, www.DentureCreamLawsuitCenter.com, and www.DentureCreamClaimCenter.org. Plaintiffs' lawyers also are actively advertising in television, print media and billboards, especially in areas with large numbers of retirees, such as Florida and Arizona. However, only time will tell if these suits go anywhere, particularly in the class-action context.

Notes

[1] Nations et al., *Denture Cream: An Unusual Source of Excess Zinc, Leading to Hypocupremia & Neurologic Disease*, NEUROLOGY, at 71, 639-643 (2008).

[2] *Id*. at 640.

[3] *Id*. at 640-41.

[4] *Id*. at 642.

[5] M. Spinazzi, *Denture Cream: An Unusual Source of Excess Zinc, Leading to Hypocupremia and Neurologic Disease*, NEUROLOGY, at 73,76 (2009).

[6] *In re Denture Cream Prods. Liab. Litig*., 624 F. Supp. 2d 1379, 1381 (J.P.M.L. 2009).

[7] *Id*.

[8] *Bates et al. v. Proctor & Gamble Mfg. Co. et al.,* No. 2051-TNW-2-200902144, *complaint filed* (E.D. Tenn. Mar. 10, 2009).

[9] *Bond et al. v. SmithKline Beecham Corp*., No. 2051-TNW-2-09-2143, *complaint filed* (E.D. Tenn. Mar. 10, 2009).

[10] *In re Denture Cream*, 624 F. Supp. 2d at 1381.

[11] 39 F.R.D. 69, 103 (1966).

[12] *In re Prudential Ins. Co. Am. Sales Practice Litig*., 148 F.3d 283, 313-14 (3d Cir. 1998).

[13] *In re Fosamax Prods. Liab. Litig*., 248 F.R.D. 389 (S.D.N.Y. 2008).

[14] *Id*. at 397.

[15] *Id*.

[16] *Id*. at 399.

[17] *Id*. at 401.

[18] *Id*. at 402.

[19] *Sutton v. St. Jude Med. S.C*., 419 F.3d 568, 575 fn. 7 (6th Cir. 2005).

[20] http://www.dentureliving.com/fixodent-denture-products/product-faq.

[21] *Bower v. Westinghouse Elec. Corp*., 522 S.E.2d 424, 429 (W. Va. 1999).