

## Blizzard, McCarthy & Nabers Denture Cream Clips

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<sup>1</sup> The *Raleigh News & Observer* piece was picked up by the *Abilene Reporter News*, the *Fort Wayne Journal Gazette*, the *Sacramento Bee*, and the *St. Louis Post-Dispatch*. It was also picked up by the website, *Lawyers and Settlements*.

<sup>2</sup> The *Fort Worth Star-Telegram* piece was picked up by the *Boston Herald*, the *Charleston Gazette*, the *Deseret News*, the *Morning Call*, the *St. Paul Pioneer Press*, the *South Florida Sun-Sentinel*, the *Time Magazine Wellness Blog* and *United Press International*.

**JANUARY 13, 2010 – THE RALEIGH NEWS & OBSERVER: DENTURE USERS BLAME NERVE DAMAGE ON ZINC (SARAH AVERY)**

Zinc in denture adhesives has been blamed in dozens of cases of nerve damage, including that of a North Carolina man who says 20 years of using the glues caused him to become disabled.

The products, Poligrip brands from GlaxoSmithKline and Fixodent from Procter & Gamble, use zinc as a bonding agent. Scientists have only recently drawn a possible link between the zinc-containing denture creams and neurological problems. Glaxo says its product is safe if used properly.

The poison is in the dose. Although zinc is an essential mineral for cell function, it can be harmful in high doses because it inhibits the absorption of other minerals. As a result, people who ingest too much zinc develop copper and iron deficiencies that can lead to severe numbness and weakness from nerve damage.

Most of those who have reported illness used excessive amounts of dental adhesive, often because their false teeth fit poorly and require more cream to form a bond.

About 40million Americans have dentures and use adhesives to secure them, and the products have long been considered benign. The American Dental Association said in its statement it knows of no confirmed cases of dental glues causing nerve damage.

"It's a pretty rare problem," said Dr. Michael Cartwright, an assistant professor of neurology at Wake Forest University School of Medicine who has treated patients with the suspected link. "There are many, many people who use denture cream who don't develop any kind of neurologic disease. We don't know why it happens in some people - if they're using large amounts [of denture cream], or if they have some other predisposition to copper deficiency."

**New consumer warning**

GSK officials, in a written statement, said the denture glue is not harmful if used normally. In addition, the company last fall began including a package insert for its Poligrip products: "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."

The insert also urges people to talk to their doctors before using Poligrip if they are also taking zinc supplements, which are popular as immune boosters to ward off colds.

The link between the dental glues and nerve damage was first noted in 2008, when scientists at the University of Texas Southwestern Medical Center published a report in a prominent medical journal. The scientists suspected dental creams were behind some patients' symptoms, and they tested tubes of adhesive for zinc, which at the time wasn't listed on the product ingredients.

The report spurred additional analyses - one finding that a denture cream contained zinc at four times the recommended daily allowance.

Many neurologists began asking patients whether they wore dentures.

Cartwright, at Wake Forest, said he first heard of the connection at a medical meeting a few years ago, and he has diagnosed some cases. He said his patients have not regained normal limb function even after the mineral imbalance is corrected. Still, he said, further harm is halted.

Johnny Howell, 53, of Winston-Salem says Poligrip was the source of zinc poisoning he suffered over at least 20 years, causing his legs to suddenly buckle beneath him. He eventually lost his job as a mechanic and had to go on disability.

"I can't walk, I can't drive," he said. "I fell down and broke a rib because of it. I broke my ankle. I cracked my wrist."

He plans to sue GSK this week. The company, which has one of its U.S. headquarters in

Research Triangle Park, faces at least 15 other lawsuits in Philadelphia, where it has another headquarters. About 70 cases have been filed against both GSK and Procter & Gamble in a federal court in Florida.

Dentures to lawsuits

Ed Blizzard, a Houston lawyer who is representing Howell and dozens of other patients, said many of the people he represents have suffered permanent disabilities, and at least one person has died.

As a result, he said, GSK's disclosure and warnings come too late. For years, he said, consumers had no idea that the tubes of adhesive contained zinc or that zinc could be so harmful in high doses.

"Glaxo says, 'Don't use the product in excess,'" Blizzard said, "as if these people were alcoholics or something. They're just trying to keep their teeth in their mouth."

Howell said he first developed symptoms in 2004 - 15 years after using the cream once a day on his upper plate and twice on the lower.

"I thought I was just clumsy," he said of his constant trips and falls. In early 2005, he was diagnosed with nerve damage. He said the cause was unknown until last year, when he went to see Cartwright and blood tests showed high zinc levels and low copper.

Howell said he continues to battle the unpredictable numbness, weakness and pain in his legs that keeps him from working and enjoying the outdoors. He depends on a walker, which makes him unable to care for his wife, who suffered a stroke several years ago and is now in a nursing home.

"I'd like to be able to bring her home," he said, "but I can't take care of her."

He is frustrated that something he relied on to improve his life may have damaged it.

"I thought I was doing good, going and getting these teeth," he said. "I hadn't taken good care of my teeth - I was the oldest of six, and my daddy left when I was 10, so I was trying to get out and work for my younger brothers."

Now, he said, he's the one who needs help.

#### **JANUARY 19, 2010 – HUFFINGTON POST: ZINC DENTURES RISK: ADHESIVES BLAMED FOR NERVE DAMAGE**

Zinc in denture adhesives has been blamed in dozens of cases of nerve damage, including that of a North Carolina man who says 20 years of using the glues caused him to become disabled.

About 40 million Americans have dentures and use adhesives to secure them, and the products have long been considered benign.

#### **JANUARY 25, 2010 – NBC MIAMI: DEADLY DENTURES KILLED MIAMI MAN (BRIAN HAMACHER)**

The widow and daughter of a Miami man who died at a South Carolina nursing facility in 2008 have filed a lawsuit against the maker of his denture adhesive, claiming his paralysis and death were a result of toxic Poligrip.

The family of Rodney Urbanek claims the 64-year-old ingested deadly levels of zinc through the product, causing him paralysis and ultimately death through pneumonia. It may be the first denture death in the U.S., the family's attorney claims.

GlaxoSmithKline, the company that makes Poligrip, said they couldn't give any specific comments on the case since it's still in active litigation.

"The case reports mentioned in the media involved excessive use or misuse of denture adhesive on a chronic basis. When the product is used as directed, the amount of zinc that might be swallowed is small and is not harmful," the company said in a statement.

Urbanek had used Poligrip for approximately 14 years, according to his family.

The lawsuit, filed in Miami, claims Urbanek was completely healthy in 2007, but just 14 months later, he was paralyzed below the waist, confined to a wheelchair and unable to lift his arms. Urbanek died a short time later, and his family's attorney said the main cause was a toxic level of zinc in his system, brought on by Poligrip.

"Rodney's case is a troubling example of what can happen when manufacturers fail to warn consumers about the risks associated with their products," said attorney Ed Blizzard, in a released statement. "The makers of these denture adhesives knew full well that high levels of zinc posed a serious threat to the health of their consumers, but did nothing."

#### **JANUARY 28, 2010 – THE SCOTSMAN: TOXIC DENTURE CREAM KILLED MY HUSBAND, SAYS WIDOW (RICHARD LUSCOMBE)**

AN AMERICAN widow has launched a lawsuit alleging that her husband was killed by his dentures.

The family of Rodney Urbanek, 64, claim he died from deadly levels of zinc ingested from a toxic denture adhesive that he used for 14 years.

It is believed to be the first case in the United States of a death blamed on poisoning from denture cream.

Mr Urbanek was healthy in early 2007, but became paralysed below the waist a few months later and confined to a wheelchair, according to the lawsuit filed against the US arm of GlaxoSmithKline. He died from pneumonia in a nursing home in 2008.

Edward Blizzard, the lawyer representing Mr Urbanek's widow Gisela, 59, and daughter Deanne, 38, said: "The makers of these adhesives knew full well that high levels of zinc posed a

serious threat to the health of their consumers, but did nothing."

A spokesman for GlaxoSmithKline insisted its product was safe, if used according to instructions. He said: "Case reports mentioned in the media involved excessive use or misuse of denture adhesive on a chronic basis. When the product is used as directed, the amount of zinc that might be swallowed is not harmful."

#### **FEBRUARY 4, 2010 – FORT WORTH STAR-TELEGRAM: SUSPECTED CULPRIT IN MINERAL WELLS WOMAN'S DEBILITATING DISORDER: DENTURE CREAM (JAN JARVIS)**

It began with a tingling sensation, as if her foot was going to sleep.

Then numbness set in. It crept up to Elizabeth Gilley's calf and onto her thigh.

Over the next six months, the Mineral Wells woman grew weaker, her skin turned pale, and she could barely walk across the room without gasping for breath.

When she collapsed in 2007, Gilley was taken to a hospital.

"The doctor didn't know how I was still conscious," Gilley said.

At first, doctors told her that she had leukemia, but tests didn't confirm cancer. CT scans, MRIs and blood tests followed. Still Gilley was no closer to a diagnosis.

After a year of seeing doctor after doctor, she finally found out what was causing the symptoms, but she could hardly believe what the physician was telling her.

"Within five minutes of seeing him, he asked me if I wore denture cream," said Gilley, 26, who was forced to get dentures as a teenager after a genetic condition ruined her teeth. "I handed him the tube; he told me to stop using it."

By then the damage was done. Gilley could no longer walk, drive a car or get around without a wheelchair. Once an active young woman who had recently gotten married, she was rarely able to leave her home.

Gilley joined a growing number of people nationwide who have filed lawsuits alleging that the makers of some denture creams knew about the health risks associated with high levels of zinc in their products and did nothing about it. Fixodent and Super Poligrip are named in class-action lawsuits filed in Tennessee last year.

Gilley's suit against GlaxoSmithKline was recently filed in Philadelphia, where the manufacturer is located. About 20 other claimants have also filed suits in mass tort court in Pennsylvania.

GlaxoSmithKline declined to comment on the litigation. But on the Web site for Super Poligrip, the manufacturer addresses issues surrounding zinc.

Both GlaxoSmithKline, the maker of Poligrip and Super Poligrip, and Procter & Gamble, the maker of Fixodent, have said that their products contain zinc at levels recognized as safe. GlaxoSmithKline's label now states that there have been reports of serious health effects from increased zinc intake over a long period. But the company notes that small amounts swallowed during normal use are not harmful and that consumers should not apply the product more than once a day.

In addition, the Food and Drug Administration classifies the creams as medical devices and does not require zinc to be listed as an ingredient.

But dozens of people have been permanently disabled after using the cream for years, and at least one person has died, said Ed Blizzard of Houston, Gilley's attorney.

"I believe this is just the tip of the iceberg," he said. "I think a lot of people out there have neuropathy and don't know it could be connected to their dentures."

## **A debilitating disease**

An estimated 35 million Americans use adhesives to secure their dentures, and most have no health problems associated with the creams. But some have developed severe neurological problems, they say, caused by ingesting dangerously high levels of zinc. Gilley developed neuropathy, which causes numbness, tingling and pain.

For years, the source of high zinc levels was a mystery. But recently researchers have observed a link between neurological problems and the use of denture cream, which contains zinc.

In 2008, researchers at the University of Texas Southwestern Medical Center reported on four young to middle-age patients who developed numbness, weakness and difficulty walking after ingesting high levels of zinc.

It's well-documented that too much zinc interferes with the absorption of copper into the bloodstream and can lead to neuropathy, said Dr. Sharon Nations, an associate professor of neurology at UT Southwestern.

The question was, Where was the zinc was coming from?

Nations suspected that denture cream might be the source after discovering that one of her patients had used the product a lot. When she learned that another had also used denture cream in large amounts, she tested a tube for zinc.

"We found it contained significant amounts," she said.

Since the patients were not getting zinc from vitamins, food or other sources, the researchers were left with one conclusion.

"The patients had no other source of the zinc," Nations said.

Those involved in the study were using on average two tubes of denture cream a week

compared with the one tube every month to six weeks that dentists recommend.

When used as directed, denture creams are safe and adverse effects are very rare, according to the Consumer Healthcare Products Association, which represents the makers of over-the-counter medicines, vitamins and other products.

It is expected that consumers would ingest some zinc from denture cream, but the amounts would be small, the association said in a statement.

The amounts ingested would be no more than the amount in 6 ounces of ground beef, six oysters or a vitamin, according to Procter & Gamble.

Blizzard said denture wearers had no reason to cut back on denture cream because until recently there was no warning against using as much as they needed.

"In fact, on the box, it said that if the amount you're using doesn't work, use more," he said.

### **Left feeling numb**

Gilley, who was not part of the study, did exactly that.

She used the cream as often as every two hours to keep the poorly fitted dentures in her mouth. Then 15 years old and a freshman in high school, she was embarrassed by the dentures, which became necessary after a genetic disorder damaged the enamel on her teeth. She was terrified that the dentures would fall out while she was eating in the school cafeteria.

She never imagined that the denture cream would lead to health problems a few years later.

Since learning about the link between her health problems and zinc, Gilley has stopped using the cream and gotten better-fitting dentures that stay in place without adhesives.

She has gradually regained some strength and moved from a wheelchair to a walker. But the

numbness still makes it difficult to walk, and she rarely leaves the apartment she shares with her husband.

In general, patients who developed neurological problems after being exposed to excessive zinc have not shown dramatic improvements, Nations said.

"Their neurological problems don't improve; they just stop progressing," she said.

Gilley, who spends her time playing with her new puppy and watching television, is still optimistic despite waves of depression.

"I do hope I get full function back," she said. "That would be so great to live life again the way I used to."

### **FEBRUARY 4, 2010 – LOUISVILLE COURIER-JOURNAL: DENTURE CREAM, ZINC UNDER FIRE; NEUROLOGICAL PROBLEMS CITED (DARLA CARTER)**

Using denture cream might seem like an innocuous thing. But if it contains zinc, you should be mindful of possible health risks, some health-care providers say.

Dr. Sharon Nations, a Texas neurologist, and colleagues have seen neurological problems in people who used large amounts of zinc-containing denture cream, such as two or more tubes a week. And similar cases have spawned lawsuits across the country, according to media reports.

Whether the denture cream is actually to blame is a matter of debate, but one thing some Kentucky dentists agree on is this: "If you're needing that much adhesive to keep your dentures in place, you need to see a dentist to get them refitted or remade," said Dr. Robert Frazer of the University of Kentucky College of Dentistry. "Most people with good-fitting dentures don't use adhesive at all. A well-fitting set of dentures don't need (you) to keep them in place with adhesive."

Also, dentists should be advising their patients to read and follow directions for denture cream use, said Dr. Mike Johnson, an Owensboro dentist who's president of the Kentucky Dental Association.

"The best advice I can give anyone concerning these things ... is read the directions on the package when you purchase the product," Johnson said. "Don't just say, 'My best friend uses this, and this is what she does.'"

Nations, an associate professor of neurology at the University of Texas Southwestern Medical Center, was the lead author of a report that appeared in the journal *Neurology* in 2008. It detailed the experiences of four patients who used large amounts of Fixodent Original, Super Poligrip Original or Super Poligrip Extra Care with PoliSeal.

Health problems among the patients included limb weakness; abnormal sensations, such as numbness or tingling; incontinence; and poor balance.

### **Call for more study**

Frazer, an associate professor in UK's restorative division, said he'd like to see more study to confirm whether denture cream can lead to such problems. "What we really need is better scientific evidence," he said.

But Nations said, "We did show that these patients had high levels of zinc, and there wasn't any other source for their zinc that we could find."

High levels of zinc can lead to copper deficiency, which is known to cause neurologic and hematologic (blood) disease, according to Nations' article. Of the four patients, she said, "I think what caused their neurologic problems was low copper (levels)."

The American Dental Association referred the *Courier-Journal* to a statement it issued last spring, saying it had no independent facts about

the cases in the journal *Neurology*. "We are not aware of any reports of neurological problems resulting from use of a denture cream following the manufacturer's instructions."

It also noted, "Patients with loose fitting dentures should see their dentist regularly for examination and appropriate care, which can reduce the need for denture adhesive products."

The U.S. Food and Drug Administration did not respond to requests for comment.

### **What to do**

If you're concerned about this issue, Nations recommends getting better-fitting dentures, switching to denture cream without zinc, or using your regular denture cream sparingly.

When using brands that contain zinc, you should only be "applying it once a day in a moderate amount, which would be just a few dots of the adhesive," Nations said.

"A tube of denture cream should last at least a month or six weeks," she said. "If you're using it more frequently and you're running out in less than a month, you're probably using too much."

Nations also cautioned against long-term use of zinc supplements. Some people take them for colds or to try to boost their immune system. But it's important not to consume more than 40 milligrams a day, she said, recalling a patient who became ill after taking 50 to 100 milligrams a day for two years.

Zinc is added to some denture adhesives to improve its bonding ability, said Frazer, a prosthodontist (a dentist who specializes in restoring and replacing teeth). Zinc-free versions are sold but "may not last as long," he said.

**FEBRUARY 9, 2010 – HUFFINGTON POST: IS YOUR MEDICINE CABINET POISONING YOU? (OP-ED: ED BLIZZARD)**

American consumers are becoming increasingly concerned about the safety of the products they use. And with good reason. Just this month, Toyota announced one of the largest vehicle recalls in our nation's history. And it seems a new recall of tainted food -- from spinach, to peanut butter, to ground beef -- is announced each week. But the products that could prove potentially hazardous are not limited to our driveways and refrigerators. One of the most dangerous places in your house might just be your medicine cabinet.

Pharmaceutical drugs often make headlines, not only for the penchant of celebrities to abuse them, but also because many are pushed through the approval process without a complete understanding of their potential side effects. Thalidomide is the most tragic historical example, when more than 10,000 children were born with deformities because their mothers took the "wonder drug."

But over the last two years, the public has learned that even over-the-counter products can prove extremely dangerous and debilitating.

Remember the commotion over acetaminophen, that ubiquitous pain reliever found in everything from Tylenol to Nyquil? We learned last year that even small doses of this medication can cause serious liver damage. In fact, it is the leading cause of liver damage in the United States. And what about Zicam nasal spray? Last year, the Food & Drug Administration pulled the cold remedy from shelves because it was causing consumers to permanently lose their sense of smell. The FDA documented more than 130 cases of consumers who suffered long-lasting or even permanent nerve damage as a result of the drug.

Now, Americans have yet another product to be wary of: denture adhesive. As strange as it sounds, dozens of consumers have been left permanently disabled by this seemingly innocuous product. The makers of popular brands of denture cream, Poligrip and Fixodent, have been adding zinc to their denture cream product for years -- and not just trace amounts.

In fact, each gram of Poligrip denture cream contains more than four times the recommended daily dose.

Consumed in large quantities over extended periods of time, zinc can cause serious neurological problems, including a condition known as neuropathy. The American Academy of Neurology published a study in October 2008 documenting the medical link between denture cream and neurological disease. This condition, which generally manifests itself through a loss of sensation or tingling in the hands and feet, is progressive and often extremely debilitating. More information on the disturbing symptoms of denture cream zinc poisoning is available online at [www.denturecreamjustice.com](http://www.denturecreamjustice.com).

As an attorney, I've seen the damage these denture creams can do first hand. Currently, I represent eight consumers who have been permanently disabled by their denture adhesives -- one of whom, Rodney Urbanek, actually died. And my clients are not alone. So far, approximately 85 lawsuits have been filed in Miami and Philadelphia against the makers of these zinc-laden Poligrip and Fixodent denture creams, GlaxoSmithKline and Proctor & Gamble respectively.

As consumers, we need to be able to trust that the products we buy are safe. But contrary to common sense, the products used most often by Americans, also tend to be the least regulated -- dietary supplements and over-the-counter drugs. It's critical that we safeguard the public from the dangers posed by those corporations that would operate with an eye on the bottom line, rather than the safety of their consumers.

**FEBRUARY 14, 2010 – ST. PETERSBURG TIMES:  
DENTURE ADHESIVES CITED IN LAWSUITS  
(RICHARD MARTIN)**

A Miami man in his 60s suddenly has trouble walking. A Colorado woman in her 40s starts losing the use of her legs. A Texas woman in her 20s feels tingling, then numbness that starts in her feet and crawls up to her thighs.

All three blame an unlikely suspect: denture adhesives.

A growing number of lawsuits are being filed against the manufacturers of popular products like Super Poligrip and Fixodent, alleging that the zinc in the adhesives is leading to serious neurological problems — and in one case, death. In Miami alone, more than 70 such cases have been filed, and although none is in Tampa Bay area courts, local pros-thodontists say their denture-wearing patients are asking how they can protect themselves.

The suits claim that denture adhesive manufacturers GlaxoSmithKline (Super Poligrip) and Procter & Gamble (Fixodent) failed to adequately warn consumers that ingesting the high levels of zinc found in many of their products could be dangerous.

Bolstering the cases are recent studies, including one headed by the University of Texas Southwestern Medical Center, which link heavy denture adhesive usage to serious neurologic disease.

Denture adhesive manufacturers "didn't tell anybody the right amounts to use. They didn't warn people that if they didn't use the right amounts that they could be crippled," said attorney Ed Blizzard, who filed a suit in Miami in December against GlaxoSmithKline on behalf of the family of Rodney Urbanek.

Urbanek, a longtime Super Poligrip user, started having trouble walking in late 2006, according to his wife, Gisela. Eventually he became paralyzed below the waist and died in May 2008 at age 64 in a hospital in South Carolina, where the couple moved after living in Miami for many years. Blizzard said an autopsy showed Urbanek's paralysis and death were linked to his use of denture adhesive.

GlaxoSmithKline officials maintain that their denture adhesive products "are safe when used as directed," spokeswoman Malesia Dunn said in an interview last week.

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Zinc is an essential mineral found in foods such as shellfish, meat, beans and cereals, and it's also sold in supplement form. Zinc helps wounds heal, keeps the immune system functioning properly and is required for proper sense of taste and smell. In denture products, zinc helps dentures adhere better to the gums.

But too much zinc can cause nausea, abdominal cramps and diarrhea, according to the National Institutes of Health's Office of Dietary Supplements. Chronic high usage can result in copper deficiency, which can cause neurologic disease. Copper helps keep blood vessels, nerves and bones healthy.

The U.S. Recommended Daily Allowance for zinc is 11 milligrams for men and 8 mg for women. Products like Super Poligrip and Fixodent contain 17 to 38 mg of zinc per gram of adhesive (there are 68 grams in a 2.4-ounce tube).

Certainly, the adhesives are not meant to be swallowed, but because they are used in the mouth, it's inevitable that users will ingest at least some of the product.

Both Super Poligrip's and Fixodent's manufacturers say on their Web sites that swallowing small amounts of adhesive is not harmful. The Fixodent Web site says the amount of zinc an average user would ingest from daily use is less than what's in most daily multivitamins, or in six oysters.

The problem, Blizzard says, is that the product instructions don't state clearly how much to use. And until last year, Super Poligrip products did not warn users of the potential dangers of ingesting large amounts of zinc.

Super Poligrip instructions tell users to "start with a small amount." But Blizzard notes the packaging also says "use more if needed."

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Rodney Urbanek often needed more adhesive. He had worn dentures since the mid 1990s. His wife said he used Super Poligrip every day, sometimes several times a day. She estimated he went through one to two 2.4-ounce tubes a week.

Super Poligrip's new product inserts say that a tube that size should last eight to 10 weeks.

In late 2006, Gisela Urbanek said her husband began to feel numbness in his legs, making it difficult to walk. He went from needing a cane to a walker in a few months. By June 2007, he could no longer feel anything in his legs.

In early 2008, Urbanek's doctors told him he had copper deficiency due to excess zinc. He stopped using denture adhesive and began taking copper supplements. His zinc and copper levels returned to normal, but he never regained feeling in his legs, Blizzard said.

Urbanek died on May 30, 2008, of respiratory distress syndrome, which Blizzard said was linked to his neuropathy.

Gisela Urbanek said her husband had no idea the denture adhesive could be dangerous. "How would he have known?" she said. "If there was some kind of warning, he would not have risked his health."

Blizzard said Mrs. Urbanek and Deanne Urbanek, Mr. Urbanek's daughter from a previous marriage, want GlaxoSmithKline to pay for what they say Super Poligrip did to Mr. Urbanek. How much? "We haven't put a number on it," Blizzard said.

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Blizzard believes Urbanek's is the only denture adhesive case that resulted in death. The others involve a range of neurological problems, some of which have improved with treatment.

The University of Texas study examined patients with various neurologic abnormalities. Each patient wore dentures and used a lot of denture adhesive. One was a 41-year-old woman with

numbness and weakness in her arms and legs. She used two tubes a week. Another woman, 42, who used three tubes a week, experienced weakness in her hands, especially in her fingers.

In both cases, the patients showed elevated levels of zinc and decreased levels of copper. But after discontinuing use of denture adhesives and receiving copper supplements, both reported improved sensation and strength.

The 2008 findings led researchers to conclude that chronic excessive use of zinc-containing denture adhesives may result in copper deficiency and serious neurologic disease.

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Though there are no known cases involving Tampa Bay residents, the issue has caught the attention of many denture wearers, said Dr. Terry Kelly, a prosthodontist at Tampa's H. Lee Moffitt Cancer Center.

"They're asking about it," Kelly said. "Many older patients are concerned."

What does he tell them? For one, the patients who have suffered disabilities from denture adhesives, such as the ones in the 2008 study, used an excessive amount.

He also tells them that denture adhesive is not the solution for ill-fitting dentures.

The American College of Prosthodontists says that ideally, dentures should fit so well, no adhesive is needed. If your dentures don't fit, you should see your doctor.

That's what Fred Trubey was doing on Friday. Kelly was fitting the 77-year-old from Lakeland for new bottom dentures. Trubey has worn dentures for more than 50 years, but only last year started using denture adhesive to help them stay in place.

Trubey said Kelly has told him of the dangers of ingesting too much denture adhesive, so he hopes a new set will do the trick.

"I want to try to use as little as possible," Trubey said.

**FEBRUARY 15, 2010 – MINOT DAILY NEWS:  
UNRAVELING A MYSTERY: PERSISTENT  
WEAKNESS, NAUSEA TRACED TO ZINC  
OVERLOAD (KATINA TENGESDAL)**

Karen Erickson, a Minot resident, reviews medical studies suggesting a link between the use of a denture adhesive and zinc poisoning. In 2007, Erickson was diagnosed with zinc induced copper deficiency.

The cause of Karen Erickson's symptoms was unknown. All she knew was that she felt weak and nauseated, starting back in 2005. In October of 2005, she sought treatment from her primary physician.

"They did some tests and they couldn't figure it out. I was just so weak. My day consisted of taking my daughter to school and staying in bed and then picking her up and coming back home," Erickson said.

Erickson was later referred to a neurologist, because she was also experiencing numbness in her hands and feet. She didn't respond to the medications prescribed. But her primary physician had noticed that in her blood work, her red and white blood cell counts were low.

Because of the blood work findings, she was referred to Dr. Stephen Makoni, hematologist and oncologist for Trinity Health. She first saw Makoni in January of 2007.

"We did a bone marrow biopsy which was reviewed at Mayo and they discovered she was short on copper, so we did copper infusions. Once we stopped, she was short again," Makoni said.

Erickson's copper deficiency showed up in the biopsy and was confirmed by a blood test. The testing also revealed that her body contained a high amount of zinc.

"Generally we all have zinc, it's a trace mineral," Makoni said. "But when you have a large amount, it blocks absorption of copper from the intestines. Copper is needed for many enzymes in the body, including for the formation of red blood cells."

**Finding the cause**

Makoni started searching for the reason Erickson had so much zinc in her system.

"I kept looking, trying to find an answer. I stumbled across some information that denture cream had a lot of zinc. I didn't think that would apply to her," Makoni said.

"Out of the blue he asked me if I used it (denture cream) and it all came together," Erickson said.

Makoni explained that zinc is a mineral used in denture creams to help them cement dentures to the gums.

"The absorption of things from the mouth is very efficient. Zinc is absorbed from the mouth and goes into the blood," Makoni said.

Now that Erickson knew the cause of her symptoms, she recalled feeling relieved and shocked.

"I thought, finally, they knew what it was. I was blown away," Erickson said. "I've learned you've got to be careful with pharmaceutical products."

Erickson continued to receive copper infusion treatments through an IV once a week for about six weeks. Makoni explained that copper can be taken orally, as pills, but they are difficult to come by. He had to special order the infusion for Erickson from out of town.

As the copper in her body was slowly replenished, Erickson's energy levels improved.

"Before treatments, it was hard for me to go watch my kids play sports, and I didn't cook supper, I was just too weak and sick. I couldn't

even walk down a flight of stairs without keeling over," Erickson said.

"Probably about the second round of treatments, I started feeling better," she added.

While her blood counts returned to normal, Erickson's neuropathy persisted. She still experiences numbness in her feet that feels like a tingling sensation. She decided to raise awareness about zinc poisoning from denture creams.

"I'm just hoping that awareness will come out of this. I decided to go through a lawsuit, because, if anything, it will help get a warning label put on the product so people will know," Erickson said.

Houston-based pharmaceutical attorney Ed Blizzard has filed a lawsuit on behalf of Erickson in Philadelphia, where the headquarters of Poligrip's maker, GlaxoSmithKline, are located. About 20 other claimants have also filed suits in mass tort court in Pennsylvania.

Now that the cause of Erickson's illness has been discovered, Makoni is in the process of writing an article for a medical journal about Erickson's case. He now advises patients using denture creams to be careful.

"People using denture creams should be careful. Some are using way more of the product than they are supposed to, using six to 20 times more than the recommended dose. Also, when they're buying creams, they should compare brands and purchase the ones that contain the least amount of zinc," Makoni said.

"People using the creams should also be careful that they're not getting any extra zinc, either through vitamins or through cold remedies containing zinc," he added.

### **Medical studies**

During the past two years, three separate scientific studies have reported a direct connection between the use of zinc-laden denture adhesives and serious neurological

disorders such as neuropathy.

In June of 2008, a study published in *Neurology*, the official journal of the American Academy of Neurology, first made the connection between denture adhesive and neuropathy. The study was the first to implicate denture adhesives as the sole culprit, concluding that "denture cream contains zinc, and chronic excessive use may result in hypocupremia and serious neurological disease."

In February 2009, a case study published in "Nature Clinical Practice Neurology" concluded that the patient suffered from myeloneuropathy and anemia due to copper deficiency spurred by her long-term use of "denture cream with a high zinc content."

Another study in August of 2009, published in "NeuroToxicology," concluded that "use of denture cream appears to be the sole source of excessive zinc in these patients."

### **FEBRUARY 18, 2010 – ASSOCIATED PRESS: ZINC IN DENTURE CREAMS CARRIES MAJOR HEALTH RISKS (MATTHEW PERRONE AND CURT ANDERSON)**

GlaxoSmithKline is taking zinc out of three Super Poligrip denture products, following hundreds of consumer reports alleging neurological damage and other problems from excessive, long-term use.

The British manufacturer said Thursday it will cease manufacturing Super Poligrip Original, Ultra Fresh and Extra Care products in the U.S. Zinc-free formulations should be available by late April, according to the company.

Zinc-based adhesives have been approved by the Food and Drug Administration for two decades, and the products are safe when used as directed.

But recent studies show that excess zinc from dental adhesives can build up over a period of years, causing loss of balance, loss of sensation in

the hands and feet, and leaving some patients paralyzed.

Federal health experts recommend 8 milligrams of zinc per day for women and 11 milligrams for men. The nutrient helps the body fight off illnesses, repair muscle and regenerate cells.

But too much zinc can purge the body of copper, another essential nutrient needed for normal brain and nervous system function.

A copper deficiency can cause anemia, as well as nerve damage, which can eventually lead to paralysis. Good food sources of copper include seafood, nuts, whole grains and meat.

Attorney Ed Blizzard, who represents several dozen plaintiffs, said Poligrip contains 38 milligrams of zinc per ounce.

Although one tube is meant to last 8 to 10 weeks, Blizzard says some of his patients were using a tube of Poligrip a week, giving them about 45 times the daily-recommended dose of zinc.

**FEBRUARY 18, 2010 – WALL STREET JOURNAL:  
GLAXO TO REMOVE ZINC FROM DENTURE  
CREAM (MARIETTA CAUCHI AND ALICIA MUNDY)**

GlaxoSmithKline PLC Thursday warned consumers about denture creams that contain zinc and said it had taken "voluntary, precautionary" measures to stop making and supplying those products, which it said have been linked with health problems if used excessively over a long period.

"We are taking these actions because we have become aware of potential health problems associated with the long-term excessive use of our zinc-containing denture adhesive products," the company said on its Web site.

Glaxo denture-cream products that contain zinc include Super PoliGrip Original, Ultra Fresh and Extra Care products. The company said it will reformulate the denture adhesives without zinc.

The drug giant has been producing its PoliGrip products since 1996 and until last year had received around 400 reports of nonspecific neurological symptoms associated with use of the products. It said this is out of a total of 8.5 million users world-wide.

However, in 2009 there were a number of adverse incidents reported in the U.S., which has triggered a number of lawsuits.

A spokeswoman for Glaxo said the company was defending the litigation but declined to comment further.

"After speaking with the FDA (Food & Drug Administration) in the U.S. and the Irish Medical Board for the European regulators, we decided to issue our own consumer advisory," she said.

Meanwhile, she said she was unaware of any formal action taken by either regulator against the company.

The Glaxo spokeswoman said the company isn't recalling any of its zinc-containing dental adhesives from shelves because "the product is safe to use if taken as directed on the instructions." It is only if used excessively over several years that the build up of zinc in the body prevents the proper absorption of copper, which in turn leads to neurological symptoms, she said.

Glaxo said it will "transition" to zinc-free versions of all its affected and related products and that 'Zinc Free' will be clearly shown on all packaging.

Glaxo already markets zinc-free denture-adhesive products, including Super Poligrip Free, Super PoliGrip Comfort Seal Strips and Super PoliGrip Powder.

Questions about possible neurological damage from zinc poisoning have spurred dozens of lawsuits against Glaxo and Procter & Gamble Co., the maker of Fixodent. A mass tort case with about 20 patients began last year in state court in Philadelphia, where Glaxo is based.

A combined federal case with more than 70 patients was established in 2009 in Miami. Plaintiffs allege several neurological problems, including crippling nerve damage impeding their ability to walk or use their hands.

There are fewer suits against P&G, according to tort lawyer Ed Blizzard of Houston. That product may contain a lower zinc concentration, according to a 2008 study in the medical journal *Neurology*.

The 2008 study in *Neurology* prompted some of the litigation. It showed "excess zinc" in some denture creams. High doses of zinc, the study said, cause copper deficiency, which has been linked to nerve damage for about a decade. The study indicated that regular use of large amounts of adhesive—more than a tube every few weeks—provided several times the recommended daily allowance of zinc. Mr. Blizzard said some patients need to use a lot of denture adhesive to keep their teeth in.

In May 2009, the American Dental Association said it hadn't found neurological problems linked to normal use of dental creams. It said patients with loose-fitting dentures, who might overapply such creams, should have their dentists adjust their dentures. The association noted that the U.S. Food and Drug Administration hasn't taken any action regarding denture adhesives.

The FDA didn't immediately comment on Glaxo's action. Dental creams are considered Class I medical devices, which pose little or no risk.

**FEBRUARY 18, 2010 – NPR HEALTH BLOG:  
GLAXO PULLING SOME POLIGRIP FROM MARKET  
OVER ZINC RISK (SCOTT HENSLEY)**

Wearing dentures isn't anybody's idea of fun. But nobody expects that the glue used to hold the darn things in place could lead to nerve damage. Glaxo removing Poligrip containing zinc from the market.

Glaxo warned about health risks from these three formulas of Poligrip. (GSK)

Amid a rising tide of lawsuits that claim some denture adhesives containing zinc have caused serious nerve problems, drugmaker GlaxoSmithKline is pulling some Poligrip products from the market while the company works on zinc-free formulas.

So be on the lookout for Super Poligrip Original, Ultra Fresh and Extra Care--all three include zinc. The company says the products are safe to use when the directions are followed. But some people use too much of the stuff or put it on more than once a day, increasing their zinc exposure.

Isn't zinc one of those minerals that's good for you? Yes, you need some zinc for your immune system, to help wounds heal and even to be able to smell and taste. But a little goes a long way--women 19 and older need 8 milligrams a day; males 14 and up need 11 milligrams a day.

As Glaxo acknowledges in its U.S. advisory, "recent publications suggest that an excessive intake of zinc-containing denture adhesives over several years may lead to the development of neurological symptoms and blood problems such as anemia."

What are the signs of nerve trouble? Numbness, tingling, problems walking and weakness in the arms and legs, Glaxo says.

Ed Blizzard, a plaintiffs lawyer, praises Glaxo's action in a statement and called it "a victory for consumers." But, he says, "it comes far too late for the hundreds--if not thousands--of people who have been crippled by zinc poisoning."

**FEBRUARY 18, 2010 – FORT WORTH STAR-  
TELEGRAM: GLAXOSMITHKLINE TO STOP  
MANUFACTURING DENTURE CREAMS THAT  
CONTAIN ZINC (JAN JARVIS)**

The maker of a popular denture adhesive said Thursday that it will stop making the product and reformulate it to remove zinc, which has been linked to neurological problems.

GlaxoSmithKline Consumer Healthcare decided to voluntarily take the action after becoming aware of potential health problems associated with long-term and excessive use of denture adhesives containing zinc. The company said in a statement that the products -- Super Poligrip Original, Ultra Fresh and Extra Care -- remain safe to use as directed on the label.

The adhesive will be replaced with a zinc-free version.

The announcement surprised Elizabeth Gilley, who recently filed a lawsuit against GlaxoSmithKline, which makes the adhesive that she started using at age 15. The 26-year-old Mineral Wells woman, who developed neurological problems after using the denture cream, was featured in a Star-Telegram article this month.

Researchers at the University of Texas Southwestern Medical Center also published a study linking zinc in adhesives to neurological disorders.

Gilley is among a growing number of denture wearers who have filed lawsuits against the adhesive manufacturers. At least 20 mass tort claims have been filed in Philadelphia, where GlaxoSmithKline is located. About 70 lawsuits have been filed in Miami against GlaxoSmithKline and Procter & Gamble.

By telling her story, Gilley said, she hoped to educate others about the dangers of using excessive amounts of denture creams containing zinc. Several years after she began using the adhesive, her legs became numb and she had difficulty walking. Today she is disabled and uses a walker. Gilley said she hopes that others don't have to go through what she has endured.

"I think I made a difference," she said. "If it's not on the market, nobody gets hurt."

GlaxoSmithKline has added the potentially hazardous material to its adhesive for decades, despite evidence that consuming large amounts of zinc over an extended period can cause serious

neurological damage, said Houston lawyer Ed Blizzard, who represented Gilley in the lawsuit.

"Today's announcement is a responsible action for GSK to take and a victory for consumers," he said. "Unfortunately, it comes far too late for the hundreds, if not thousands, of people who have been crippled by zinc."

GlaxoSmithKline said it will transition to zinc-free versions of its adhesives. "Zinc-Free" will be clearly printed on the packaging.

### **FEBRUARY 18, 2010 – RALEIGH NEWS & OBSERVER: GSK TO HALT SALES OF DENTURE ADHESIVE POLIGRIP (SARAH AVERY)**

GlaxoSmithKline announced today it will stop making, selling and advertising its Super Poligrip brands of denture adhesives that contain zinc.

The announcement comes after numerous people, including a Winston-Salem man, said they suffered permanent neurological damage when they ingested the mineral, which had been included as an adhesive. Many consumers used large amounts of the creams to keep ill-fitting dentures in place.

In its statement, GSK officials urged people who have used the products for years in excessive amounts to switch immediately to zinc-free brands. Last fall, the company added a consumer warning in packages of the products, which include Super Poligrip Original, Ultra Fresh and Extra Care.

Zinc-free brands are Super Poligrip Free, Super Poligrip Comfort Seal Strips and Super Poligrip Powder.

Consumers who have experienced numbness, tingling and weakness in the arms and legs were encouraged to talk to their doctors.

Johnny Howell of Winston-Salem said he blames his disability on years of using Poligrip products. His legs buckle unexpectedly, causing him to fall and injure himself. He cannot drive, nor work. He

said today he is pleased the company will no longer sell the products.

"I hope it is a victory, because the fact that it could happen to me, it could end up hurting or killing someone else," Howell said.

As it has in the past, the company stressed that when used according to package directions - small amounts once a day - the level of zinc was safe.

**FEBRUARY 19, 2010 – ST. PETERSBURG TIMES: SUPER POLIGRIP TO GO ZINC-FREE AFTER CONSUMER COMPLAINTS (RICHARD MARTIN)**

Facing scores of lawsuits from consumers who say denture adhesive caused them serious health problems, the maker of Super Poligrip announced Thursday that it will stop making and distributing all its denture products that contain zinc.

The manufacturer, GlaxoSmithKline, also warned consumers of the "potential health risks associated with long-term excessive use" of the products, which may include numbness, tingling or weakness in the arms and legs, difficulties with walking and balance and anemia.

The action follows medical studies correlating zinc in denture products with neurological damage, and news reports such as one in Monday's St. Petersburg Times.

Glaxo spokeswoman Malesia Dunn said that retailers can sell current stocks of Super Poligrip Original, Ultra Fresh and Extra Care but that reformulated zinc-free versions should be available by late April or early May.

The company already makes three products that do not contain zinc: Super Poligrip Free, Powder and Comfort Seal Strips. It says products with zinc are safe when used as directed, but it acknowledged some consumers use more than recommended.

The advisory says consumers who use more than

the amount directed should stop using it and talk to their doctors. Dunn said that although the action was voluntary, the company consulted the U.S. Food and Drug Administration, which regulates denture adhesives. "They were in agreement with our action," Dunn said.

It's up to stores to decide whether to sell the three products. Walgreens will continue to do so, company spokesman Robert Elfinger said, noting the retailer was assured the products are safe when properly used.

Though zinc is an essential mineral, chronic high usage can deplete the body's stores of copper, leading to neurologic disease. A 2008 study by the University of Texas Southwestern Medical Center examined patients with various neurological problems and traced the cause to their use of products such as Super Poligrip and Fixodent.

Zinc helps with adhesion. Although well-fitting dentures require little or no adhesive, wearers who have poor fit can require a lot of adhesive, even two or three tubes a week.

More than 100 lawsuits have been filed across the country against GlaxoSmithKline and Procter & Gamble (makers of Fixodent), including more than 70 in Miami. The suits allege the companies failed to warn consumers of zinc's hazards. Neither firm listed zinc, which was approved for use in adhesives by the FDA 15 years ago, on their labels until after the 2008 study.

Ed Blizzard, a Miami lawyer who has filed several suits, called the announcement "a responsible action for GSK to take and a victory for consumers," but said it came years too late.

Blizzard represents the family of Rodney Urbanek, a longtime Miami resident who died in 2008 in South Carolina at age 64 of respiratory distress syndrome, linked to neurological problems caused by longtime use of Super Poligrip.

Urbanek's wife, Gisela, said she was pleased with Thursday's announcement.

"That is wonderful," she said from her home in Little River, S.C. "Of course, it's too late for my husband and for me, but I'm very happy that at least other people are not going to go through what my husband went through."

Procter & Gamble, maker of Fixodent, did not return calls.

Though none of the lawsuits is believed to involve any Tampa Bay residents, more than 100 people contacted the Times in response to Monday's story. Most reported having similar neurological problems to those mentioned in the story.

Larry Raes, 61, of Seminole, has worn dentures for the past four to five years and uses Super Poligrip two or three times a day to help keep them in place — package directions say it should be used once a day. Last summer, his legs "started feeling weak and rubbery," he said.

His doctor attributed the problem to his weight. "But I know it's not my weight. I've been 228 pounds for the last 10 years," said Raes, who is 5 feet 9.

Raes said he plans to see his doctor to find out if denture adhesive might be the cause.