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# HPS Newsletter

Hospital Pharmacy Management



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## The Acid Test for Enamel-Saving Toothpastes

*By Laura Johannes  
The Wall Street Journal  
November 3, 2010*



Toothpaste makers are pitching enamel-strengthening toothpastes that they say harden the tooth's protective layer, making it more resistant to attacks from acids found in foods and beverages such as soda, orange juice, and even pickles. Scientists say the toothpastes do make enamel more acid-resistant—but not enough to protect you if you guzzle soda all day.

Enamel is a thin covering over teeth made from an organic matrix and minerals, largely crystals of calcium phosphate, says scientist George Stookey, chief executive of Therametric Technologies Inc., a Noblesville, Indiana firm that sells and tests dental products. Enamel is vulnerable both to decay, caused by acids in bacteria, and to erosion, defined as direct assault from acids from food and drink, scientists say. The biggest culprits include diet and regular soda, citrus beverages, red wine and some sports drinks.

Everyone is vulnerable to acid erosion, but as we age the problem worsens with a decrease in production of saliva—which both washes away acids and neutralizes them. Some medications also decrease saliva production.

## Acid Fighters

A number of toothpastes that claim to combat acid erosion and strengthen enamel are now on the market. Crest Pro-Health Enamel Shield's label says it "protects against acid attack." Sensodyne ProNamel says it "protects against the effects of acid erosion." Colgate Total's line includes an "Enamel Strength" version. A CVS store brand promises it "helps harden tooth enamel with acid protection formula."

The claims are often based on the presence of fluoride, which scientists say combines with minerals in your mouth to create a crystal called fluorapatite on the surface of your teeth. Some of the toothpastes, including Crest's Enamel Shield, Sensodyne ProNamel and Squigle Inc.'s Enamel Saver, are also formulated to be less abrasive to protect your enamel from rubbing off when brushing. (Squigle is a manufacturer of a small brand of toothpastes it says are non-irritating to the mouth.)

Scientists give mixed reviews to the claims. They say it is incorrect to say a toothpaste can strengthen enamel as it doesn't make teeth physically stronger against shearing forces—such as biting into a piece of popcorn. The products do make the tooth surface more resistant to acids in the diet, says John Featherstone, Dean of the University of California School of Dentistry in San Francisco.

While dentists agree toothpastes can help protect enamel, you should still drink acidic beverages in moderation. "You can't drink erosive foods and drinks in high frequency and expect toothpaste to protect you," says Mark S. Wolff, a professor and chairman of the department of cariology and comprehensive care at New York University College of Dentistry.



Regardless of the toothpaste you use, it is important not to brush your teeth immediately after drinking acids as that is when enamel is most vulnerable to wear from brushing, adds Teresa Marshall, an associate professor at the University of Iowa College of Dentistry in Iowa City. It's a good idea to take a few sips of water after drinking or eating acids, scientists add, and sugar-free gum can help by stimulating saliva production.

### Looking at the Labels

As for toothpastes touting enamel strengthening, an informal inspection of labels in pharmacy aisles found the toothpastes often had nearly identical ingredients to other products by the same manufacturers that don't make enamel claims. Some of the distinction, companies say, involves proprietary differences in proportions of ingredients.

Scientists say any well-designed fluoride toothpaste will make enamel more acid resistant. The enamel-strengthening claims on the label are "a marketing gimmick," says Dr. Featherstone, who has done paid consulting for a number of

toothpaste makers. Consumers should choose toothpaste with a taste they like, as they'll use it more, he says. He recommends major brands because a lot of research goes into proper formulation.

Procter & Gamble says its Crest Pro-Health Enamel Shield is the result of more than a decade of research and seven separate inventions. The company says the term "strengthens enamel" on the label refers to making teeth more chemically resistant to acid. GlaxoSmithKline, maker of Sensodyne ProNamel, says that, while fluoride doesn't significantly harden normal tooth enamel it does have a hardening effect on enamel that has been softened by acid erosion. Colgate-Palmolive declined to be interviewed.

At least two companies—P&G and GlaxoSmithKline—have published studies showing their toothpastes help protect enamel in test subjects wearing either crowns or appliances with test teeth in them. (This type of research allows scientists to perform controlled tests, such as deliberately creating acid erosion on the test teeth.) However, there aren't enough well-designed studies directly comparing one toothpaste with another to determine if one toothpaste is really better than another, scientists say.

### Extra Fluoride Helps?

Based on ingredients, there are some differentiation points. Colgate's new ProClinical Daily Renewal for Enamel, has 1,500 parts per million of fluoride—more than most toothpastes, according to the company's website. Sensodyne ProNamel is specially formulated so that more fluoride is available, enhancing the process of remineralizing enamel,

GlaxoSmithKline says. Scientists say extra fluoride is likely to have at least a small additional effect on enamel—but more research is needed.

P&G's Crest Pro-Health Enamel Shield, which came out last year, is made with a particular type of fluoride called stannous fluoride. In addition to forming fluorapatite crystals like other fluorides, stannous fluoride also has a toxic effect on acid-producing mouth bacteria, says biochemist Matthew J. Doyle, director of global research and development for P&G's oral-care division. Stannous fluoride also protects against tooth sensitivity by blocking small tunnels in the teeth, he adds.

Crest's Pro-Health Enamel Shield also has sodium hexametaphosphate, an ingredient that forms a protective film over the teeth that lasts six or seven hours. "It's a sacrificial layer that protects the surface of the tooth," Dr. Doyle says.



### Painkiller Darvon Taken Off Market After Heart Risk Shown

By Rob Stein  
The Washington Post  
Saturday, 11/20/2010

A controversial prescription painkiller was pulled off the market Friday [11/19/2010] at the request of federal regulators because of concerns the drug can cause fatal heart problems.

Xanodyne Pharmaceuticals Inc., of Newport, Kentucky, which makes Darvon, agreed to

withdraw the medication at the request of the Food and Drug Administration, the agency said.

Companies making generic versions of the drug, known as propoxyphene, will also remove their products, the FDA said.

The FDA sought the withdrawal after receiving new data showing the drug put patients at risk for potentially fatal heart rhythm abnormalities, the agency said.

"These new heart data significantly alter propoxyphene's risk-benefit profile," the FDA's John Jenkins said in a statement, "The drug's effectiveness in reducing pain is no longer enough to outweigh the drug's serious potential heart risks."

Doctors should stop prescribing the drug and patients taking it should immediately contact their physicians to discuss switching to another medication, the FDA said.

The opioid, approved by the FDA in 1957 to treat mild to moderate pain, is sold under a variety of names, including Darvon, which is the drug alone, and Darvocet, which is the drug combined with acetaminophen.

The FDA has received two requests to remove the drug from the market since 1978 but had previously determined the benefits outweighed the risks. In January 2009 an FDA advisory committee recommended pulling the drug. But in July 2009 the agency decided instead to leave it on the market with strong new warnings about the risks and required the company to conduct a new study assessing its safety.

Friday's action was based on the results of that study, which showed that "even when taken at recommended doses, propoxyphene caused significant changes to the electrical activity of the heart" that can cause

serious problems, including sudden death, the FDA said.

"With the new study results, for the first time we now have data showing that the standard therapeutic dose of propoxyphene can be harmful to the heart," said Gerald Del Pan, the FDA's Director of the Office of Surveillance and Epidemiology.

Consumer advocates welcomed the announcement but criticized the agency for failing to act sooner. Britain pulled the drug six years ago and the rest of Europe removed it more than a year ago, they noted.

About 120 million prescriptions have been filled for the drug in the U.S. since Britain removed the drug, said Sidney Wolfe of Public Citizen's Health Research Group, which has long called for the drug's removal.

## Treatment "Vaccine" For Advanced Prostate CANCER

Lexi-Comp  
www.lexi.com  
Dr. Alan P. Agins

The FDA approved a new therapy for certain men with advanced prostate cancer. Although the term vaccine usually invokes the concept of disease prevention, this new therapy, called Provenge, is actually the first vaccine approved to treat cancer rather than prevent cancer. In this case, it is indicated for asymptomatic or minimally symptomatic metastatic, hormone-refractory prostate cancer. Remember, in this country, prostate cancer is the second most common cancer in men, after skin cancer.

Provenge (sipuleucel-T) is considered an "autologous cellular immunotherapy." It is produced by taking cells that express the antigen *Prostate*

*Acid Phosphatase (PAP)* from an individual patient's tumor and incorporating the cells into a vaccine consisting of the patient's own blood cells and a proprietary fusion protein that serves as an immune system stimulant. The immune cells are then returned to the patient in a three-dose schedule given intravenously at about two-week intervals.

Provenge was tested in a randomized, double-blind, placebo-controlled, multicenter trial involving 512 CRPC patients. Patients receiving the new treatment showed an increase in overall survival of 4.1 months, with a median survival of 25.8 months compared to 21.7 for the group not receiving it. On the downside, nearly all participants had an adverse reaction of some kind, although most were mild or moderate, and included chills, fatigue, fever, back pain, headache, joint ache, and nausea. However, about 1 in 4 patients had a serious adverse reaction to Provenge, including acute infusion reactions and stroke.

Of course, all this comes with a hefty price tag. A full treatment is expected to cost \$93,000. The manufacturer defends that price, saying it was in line with those of other cancer drugs in terms of cost per extra month of life provided by the drug. On the upside, the approval of this novel type of treatment is expected to spur the development of "treatment vaccines" for other cancers.

WISHING YOU  
LOADS OF LOVE  
AND LAUGHTER  
FOR THE HOLIDAYS





### November: National Peanut Butter Lovers Month

Considered by many the symbol of American snacks, peanut butter has been a staple of U.S. families for more than a century.

- ◆ An 18 oz jar of peanut butter needs 850 peanuts to be made.
- ◆ Peanuts are not actually nuts: They are legumes and grow underground.
- ◆ Peanuts account for 2/3 of the total snack "nuts" consumption in the U.S.A.
- ◆ The world's largest peanut is 20 feet tall, and it's currently kept in Turner County, Georgia.
- ◆ One acre of peanut crop yields 2860 pounds of peanuts, enough to make 30,000 peanut butter sandwiches.
- ◆ The peanut's nickname is goober peas.
- ◆ There are about 50,000 peanut farms in the US.

Americans eat 700 million pounds every year (3lbs per person), which could theoretically cover the entire floor of the Grand Canyon.

## Severe Sepsis Can Lead to Memory Problems

*CNN Health  
By Leslie Wade  
October 26, 2010*

Advances in intensive care medicine are helping older Americans survive severe sepsis, an overwhelming infection, but according to new research, these survivors are often left with major memory problems and physical limitations for years after infection.

Researchers presenting their findings in the *Journal of the American Medical Association* found that even older adults who were functioning independently before sepsis often came home from the hospital needing full-time care because they now had pre-dementia.

"If you look at the risk of moderate to severe cognitive impairment, people with severe sepsis were three times more likely to develop that after sepsis than before," says study author Theodore Iwashyna, critical care doctor at the University of Michigan Medical School.

The study monitored the health of more than 1,000 older adults who developed sepsis, comparing their physical and mental capabilities when healthy to those after they got sick. The researchers used data from a study nationally representative of older Americans called the Health and Retirement Study and had access to years of detailed health information on the patients.

Previous research often attributed declines in mental and physical health after sepsis to underlying health problems beforehand. But these researchers, finding that even healthy, mentally sharp adults experienced significant declines,

suggest that the sepsis itself, and the treatment strategies afterwards, may be playing a major role in the downturns in health.

"This new disability that people develop is often associated with 40 hours of care a week. People come home from the hospital after having survived and their loved ones have a new full-time job," explains Iwashyna. "Overall 60% of people had worse function afterwards than they did before," he adds.

Dr. Derek Angus, chairman of the Department of Critical Care Medicine at the University of Pittsburgh School of Medicine, wrote an accompanying editorial. He has no ties to the current study and says the research may help change current medical practice. "The major advance in this study is it took a concern that was being raised amongst a number of investigators, but a concern that couldn't be proven and has shown this is very likely a real phenomenon," he said.



Severe sepsis is the most common non-heart related reason for a person to end up in a hospital's intensive care unit. More than 750,000 people in the United States are affected by this condition each year, mostly the elderly. Iwashyna says sepsis can develop in patients with a wide range of illnesses such as

pneumonia, diabetes, urinary tract infections, those with compromised immune systems, and other health problems.

When someone develops sepsis, instead of attacking the infection at the site, the body mounts an overly aggressive immune response and ends up turning on itself, often damaging vital organs such as the heart, lungs, and kidneys. If blood pressure drops too drastically, doctors suspect the brain and other vital organs don't get enough oxygen to function properly, often leaving people physically and mentally impaired.

Iwashyna says more research is needed to develop better treatment strategies for patients with severe sepsis and therapies to minimize the mental and physical impairments seen in patients. In the meantime, he suggests people try to prevent the condition by getting pneumonia and flu vaccines and, if diabetic, getting excellent care.

If a loved one does develop sepsis, it's important to talk to your doctor about physical mobility and rehabilitation exercises, but just as important, strategies and therapies to help the brain function better.

### Frequency of Colds Dramatically Cut With Regular Exercise

*Medical News Today  
By Christian Nordqvist, 11/2/10*

If you want to reduce the frequency and severity of symptoms of colds, you should exercise at least five times a week and remain physically fit, US researchers report in the *British Journal of Sports Medicine*. They stress that not only do fit people have much fewer colds, but also when they do, their symptoms are significantly milder compared to those who do not work out regularly.

Researchers from North Carolina monitored upper respiratory tract infection frequency and symptom severity over a 12-week period during autumn/winter in 2008 on 1,000 individuals aged 18 to 85. Sixty percent of them were female and 40% were aged 19 to 39. Twenty-five percent of them were over sixty years of age while 40% were middle aged.



Information was gathered on how often they did aerobic exercises. The participants were also asked to rate their levels of fitness with a 10 point validated scoring system. Other data was collected, including participants' diet, lifestyle, and recent stressful occurrences—factors which can have an impact on an individual's immune system response, the authors explained.

Cold symptoms were present for an average of 13 days during the winter and eight days during the fall. The researchers reveal married older men seem to catch colds less often.

However, after factoring out the most significant factors linked to upper respiratory tract infections (colds) the scientist found that an individual's level of fitness, as well as exercise frequency, had the biggest impact in reducing occurrences and severity of colds.

Those who were physically fit and did exercise at least five times each week had a 43% to 46% lower frequency of colds compared to people who only exercised once a week at the most.

The fittest participants had a 41% lower symptom severity, while regular exercisers' severity of symptoms was reduced by 31%, the authors wrote.

The average American adult has two to four colds each year. US

children have an average of between 6 and 10 colds annually. The economic toll of colds on the American economy is estimated to be approximately \$40 billion annually.

The researchers say that exercise sessions trigger a temporary increase in immune system cells that circulate within the body. Although immune systems cell levels soon return to normal after exercise, they probably improve the body's surveillance of pathogens—harmful bacteria, viruses, and other organisms. Improved pathogen surveillance leads to fewer and less severe infections.

### *Is Laughter Contagious?*

*It is often said that laughter is contagious. As it turns out, laughter may be good for our health too.*

*Laughter can:*

- ☺ *Relieve pain by causing the body to break the pain-spasm cycle or produce natural pain killers.*
- ☺ *Enhance your oxygen intake, which stimulates your heart, lungs, and muscles.*
- ☺ *Increase endorphins your brain releases.*
- ☺ *Improve your immune system by decreasing the negative effects stress has on your body.*
- ☺ *Increase your heart rate and blood pressure and then cools it down, leading to a relaxed mood.*
- ☺ *Soothe tension by stimulating circulation and aiding in muscle relaxation.*
- ☺ *Stimulate the release of neuropeptides that help fight disease and stress.*
- ☺ *Help you to connect socially with others.*

*Today, help provide this natural medicine to yourself and others by finding a way to share a laugh.*



**Small**

## **Doses.....**

**By Mike Petry, MS, RPh  
Clinical Pharmacist**

### **Misuse of Opioids and Benzodiazepines on the Rise**

Rates of prescription drug overdose deaths increased rapidly in the United States (US) from 1999 through 2006. However, review and analysis of mortality data does not fully portray the morbidity associated with prescription drug overdoses. Data from emergency department (ED) visits can be used to better understand recent national trends in drug-related morbidity. The Drug Abuse Warning Network (DAWN) is a public health information system run by the federal government that tracks the impact of drug use, misuse, and abuse in the US by monitoring drug-related hospital ED visits.

DAWN is a division of The Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA is a federal government agency established in 1992 to work in the areas of substance abuse and mental health services. DAWN uses a sample of EDs to estimate national ED visit rates. It collects data from a stratified, simple random sample of approximately 220 nonfederal, short-stay, general hospitals that operate 24-hour EDs in the US. DAWN's sampling is based on the American Hospital Association annual survey database and is updated annually. The DAWN sample is designed to produce estimates and trends for individual metropolitan areas (12 in 2008) and the US overall. Trained DAWN reporters review the medical charts of all patients

treated in the participating hospital EDs to identify visits for conditions induced by or related to drug use. DAWN reporters record information from the ED medical records using standard abstraction forms. DAWN does not conduct interviews or follow-ups with clinicians, patients, or family members. Rates presented are based on the numbers of ED visits weighted so that they are representative of the entire country.

A new study done by the Centers for Disease Control and Prevention (CDC) and SAMHSA was recently published in *Morbidity and Mortality Weekly Report* (2010; 59:705-709) using the latest DAWN data. The study demonstrates a dramatic increase in the rates of ED visits involving nonmedical use of prescription drugs. The data collected covered 2004 to 2008 (the most recent five years for which data were available).

The DAWN review showed that the number of ED visits for the nonmedical use of opioid analgesics increased 111% during the five-year period; the number of ED visits for the nonmedical use of benzodiazepines rose 89% during the same period. An estimated 1.6 million ED visits for misuse and abuse of commercially available drugs occurred in 2004. By 2008, that number had increased to 2 million. Illicit drugs were involved in 1 million cases in both years; nonmedical use of prescription and over-the-counter drugs accounted for 500,000 visits in 2004 but rose to one million visits in 2008. The number of cases involving the nonmedical use of opioid analgesics increased from 144,600 in 2004 to 305,900 in 2008, with the highest number of ED visits recorded for oxycodone (OxyContin®), hydrocodone (Vicodin®, Norco®) and methadone (Dolophine®). Cases involving the nonmedical use of benzodiazepines increased from

143,500 in 2004 to 271,700 in 2007, with alprazolam (Xanax®), clonazepam (Klonopin®), diazepam (Valium®), lorazepam (Ativan®) and zolpidem (Ambien®) being the most common agents.

Over the five years studied, the largest increases in misuse or abuse rates of prescription drugs occurred in people 21 to 29 years old. In 2008, the misuse rates for both opioids and benzodiazepines increased sharply after age 17 and peaked in the 21-24 year old age group before declining after age 54. The researchers did question the accuracy and completeness of the information regarding the drugs involved, and whether the drugs had been prescribed for a valid medical reason. Despite these potential flaws, the underlying message is still quite clear.

One major cause for this dramatic increase in this problem is the increase in the prescribing of these drugs. For example, CDC estimates that 8 million people in the United States use opioids long-term to manage their chronic pain, which is markedly higher than a decade ago. ED clinicians also attribute the problem to many other possible reasons. The economic problems experienced by many patients may motivate them to use illicit drugs as an escape. Patients that can't afford traditional health care who have a chronic pain condition may be self-medicating with opioids. Several patients report that they buy their prescription drugs online. Patients no longer have to go to the street corner to buy drugs, they just have to turn on their computer. Doctor shopping, drug diversion and other established strategies are still occurring as well.

As a result of this study, CDC has acknowledged that efforts to prevent misuse of these drugs have not been effective, calling for "stronger measures to reduce the diversion of prescription drugs to nonmedical purposes."